In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-486V

(Filed: October 27, 2020)

GINGER M. MARTIN, *and* CATHERINE J. O'QUIN, *as Representatives of ESTATE OF HEAVENLY S. LEE*,	*	To Be Published
Petitioners,	*	Denying Entitlement to Compensation; Causation-in-Fact; Significant Aggravation; Dandy-Walker Variant; Vermian Hypoplasia; Cerebral Dysgenesis; Diffuse Cortical Atrophy; Thinning Corpus Callosum; Diphtheria-Tetanus-acellular Pertussis ("DTaP") Vaccine; Inactivated Poliovirus ("IPV") Vaccine; Haemophilus influenzae b ("Hib") Vaccine; Pneumococcal conjugate ("Prevnar") Vaccine
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Claudia Gangi, U.S. Department of Justice, Washington, D.C., for respondent.

DECISION[1]

Roth, Special Master:

On July 18, 2013, Ginger Martin and Catherine O'Quin ("Ms. Martin," "Ms. O'Quin," or "petitioners") filed a petition on behalf of Heavenly S. Lee, a minor child,[2] for compensation under

[1] This Decision has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). However, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The Petition was originally filed by the petitioners as Heavenly's guardians. Sadly, Heavenly passed away during the pendency of this litigation, and the case caption was amended to reflect the petitioners as acting on behalf of Heavenly's estate. *See* ECF Nos. 115, 117.

the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.[3] (the "Vaccine Act" or "Program"). The petition alleged, as a result of diphtheria-tetanus-acellular pertussis ("DTaP"), *haemophilus influenzae* b ("Hib"), inactivated poliovirus ("IPV"), and pneumococcal conjugate ("Prevnar") vaccines received on August 2, 2010 and September 28, 2010, that Heavenly suffered seizures and encephalopathy associated with brain atrophy. Petition at 1-2. Petitioners alleged that Heavenly's seizure disorder, microcephaly, and developmental delays were caused-in-fact by her vaccinations. *Id*. at 2. On June 20, 2017, petitioners filed an Amended Petition ("Am. Pet.") reiterating their original causation-in-fact claim and further alleged that the vaccinations significantly aggravated a preexisting Dandy-Walker Variant. Am. Pet. at 2, ECF No. 69.

This is the unfortunate case of a baby born with Dandy-Walker variant and multiple associated congenital brain anomalies. Pet. Ex. 4 at 9. Petitioners were granted sole custody of Heavenly on July 18, 2012 by Order of the Circuit Court of Baldwin County, Alabama. Tr. 8-9; Pet. Ex. 17.

An entitlement hearing was held on June 18 and 19, 2018, in Mobile, Alabama. For the reasons stated herein, I find that petitioner has not proffered sufficient evidence to demonstrate entitlement to compensation.

The record fails to support more likely than not, that Heavenly suffered a post-vaccination encephalopathy or other causally related reaction following her August 2, 2010 or September 28, 2010 vaccinations that later manifested as neurological or developmental injury.[4] Further, the contemporaneous medical records fail to establish a proximate temporal reaction to either set of vaccinations to support an encephalopathy following her vaccinations. None of Heavenly's treating physicians attributed her condition to any of the vaccinations she received, except for Dr. Mauney whose opinion is addressed at length below.

Rather, the records support the evolution of global neurological delay resulting from congenital brain anomalies manifesting as failure to thrive, microcephaly, failure to meet milestones, visual impairment, hypotonia, and seizure disorder. The November 2010 MRI revealed the cause of the neurological damage to be Dandy-Walker variant, cerebral dysgenesis, vermian hypoplasia, decreased myelination, cortical atrophy, and microcephaly. Pet. Ex. 4 at 118. Heavenly's encephalopathy was chronic and the result of congenital brain anomalies, not the result of a vaccine-related injury as opined by Drs. Holmes and McGeady.

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[3] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[4] When compared to the rare cases where petitioner has established an encephalopathy following vaccination, not including Table claims where causation is assumed, the vaccinated child developed a high fever within 48 hours of vaccination, and displayed crying, sleeplessness, significant motor problems, and seizures, all of which were documented in the medical record. *See, e.g., Noel ex rel. Estate of Noel v. Sec'y of Health & Human Servs.*, No. 99-538V, 2004 WL 3049764 at *16 (Fed. Cl. Spec. Mstr. Dec. 14, 2004).

I. Procedural History

The petition was filed on July 18, 2013. ECF No. 1. Petitioners filed medical records through September of 2013. *See* Pet. Ex. 1-16, ECF Nos. 6-8; Pet. Ex. 18-22, ECF Nos. 11-12. This matter was initially assigned to Special Master Hamilton-Fieldman and was reassigned to me on October 22, 2015. ECF No. 46.

After multiple extensions, petitioners filed an expert report from Weldon Mauney, M.D.[5] Dr. Mauney is a neurologist at Child Neurology Center of Northwest Florida, who began treating Heavenly in October of 2011. Pet. Ex. 23 at 1, ECF No. 24; *see also* Motion, ECF No. 19; Non-PDF Order, issued Mar. 28, 2014; Motion, ECF No. 21; Non-PDF Order, issued Apr. 23, 2014; Motion, ECF No. 22; Non-PDF Order, issued June 30, 2014; Motion, ECF No. 23; Non-PDF Order, issued July 25, 2014. Dr. Mauney opined that the DTaP vaccine received by Heavenly caused her to suffer a static encephalopathy. Pet. Ex. 23 at 3, ECF No. 24.

On October 9, 2014, respondent filed an expert report from Dr. Holmes. Dr. Holmes received his medical degree from the University of Virginia and completed residencies in pediatric and pediatric neurology at Yale University School of Medicine and University of Virginia School of Medicine, respectively. Resp. Ex. B at 1. He is board-certified in pediatrics, neurology, and clinical neurophysiology. *Id*. He currently holds appointments in both pediatrics and neurological sciences at the University of Vermont College of Medicine. Tr. 234. Dr. Holmes has treated "hundreds" of pediatric patients with congenital brain defects and approximately 10 to 20 patients with Dandy-Walker variant. Tr. 235.

Thereafter, respondent filed his Rule 4(c) Report ("Resp. Rpt.") on November 13, 2014. *See* Resp. Ex. A-B, ECF No. 26; Resp. Rpt., ECF No. 27. Respondent submitted that "the court need not consider Dr. Mauney's opinion, as it is based on faulty facts" and did not satisfy the *Althen* criteria. Resp. Rpt. at 7, ECF No. 27.

On November 20, 2014, following a status conference, an order was issued requiring petitioners to file a supplemental expert report by February 4, 2015. *See* Scheduling Order at 1, ECF No. 28. Petitioners filed for five extensions of time within which to file their supplemental expert report; all were granted *See also* Motion, ECF No. 29; Order, ECF No. 30; Motion, ECF No. 31; Order, ECF No. 32; Motion, ECF No. 43; Order, ECF No. 44; Motion, ECF No. 48; Non-PDF Order, issued Nov. 2, 2015; Motion, ECF No. 49; Non-PDF Order, issued Dec. 1, 2015.

During this timeframe, petitioners filed additional medical records, substituted Mr. Gage as their attorney of record, and filed a Statement of Completion. *See* ECF No. 34; Pet. Ex. 24, ECF No. 36; Pet. Ex. 25, ECF No. 37; Pet. Ex. 26, ECF No. 38; Pet. Ex. 27, ECF No. 41; Pet. Ex. 28, ECF No. 42; ECF No. 45.

On January 4, 2016, petitioners filed an expert report from Dr. Steinman rather than a supplemental report from Dr. Mauney. Pet. Ex. 30; ECF No. 50. Dr. Steinman is a neurologist at Stanford University. Pet. Ex. 30 at 1. He graduated from Dartmouth College with a degree in physics and attended Harvard Medical School, where he also completed a fellowship in chemical

[5] Dr. Mauney did not testify at hearing and a CV was not submitted.

neurobiology. *Id*. During his residency at Stanford University Hospital, he completed a fellowship in chemical immunology. *Id*. He has been a professor at Stanford since 1980, with appointments in neurology, neurological sciences, pediatrics, and genetics. *Id*. Dr. Steinman is board certified in neurology and has published hundreds of articles on the immunological aspects of neurologic disease. *Id*. He is considered an expert on multiple sclerosis and holds several patents for therapies used to treat MS. *Id*. Dr. Steinman's CV was filed on February 4, 2016, and supporting medical literature was filed on March 7, 2016. Pet. Ex. 30, ECF No. 51; Pet. Ex. 31-39, ECF No. 53; Pet. Ex. 40-48, ECF No. 54; Pet. Ex. 49-53, ECF No. 55.

On April 22, 2016, respondent filed an expert report and supporting literature from Dr. McGeady. Resp. Ex. C-L. Dr. McGeady is a pediatrician and an allergist/immunologist. Tr. 314. He received his medical degree from Creighton University and completed a residency in pediatrics at St. Christopher's Hospital in Philadelphia and a fellowship in psychiatry and allergy at Duke University. Resp. Ex. D at 1. Dr. McGeady began teaching at Jefferson Medical College in 1974 and was elevated to Professor of Pediatrics in 2005; he is also the director of the Allergy and Immunology Training Program. *Id*. He has served as the medical director for Children's Heart Hospital, Children's Rehabilitation Hospital, and Jefferson Park Hospital, all in Philadelphia. *Id*. Dr. McGeady also served as the chief of the allergy, asthma, and immunology division at duPont Hospital for Children from 1996 to 2006. *Id*. He is board certified in pediatrics, allergy and immunology, and diagnostic laboratory immunology. *Id*. Dr. McGeady's report, Resp. Ex. C, was later refiled due to filing error. *See* Motion, ECF No. 60; Non-PDF Order, issued May 9, 2016; Resp. Ex. C, ECF No. 61.

After a status conference on June 30, 2016, petitioners were ordered to file any supplemental expert reports by August 29, 2016, and a joint status report identifying potential hearing dates. *See* Order, issued June 30, 2016, ECF No. 62. On August 29, 2016, a prehearing order was issued setting the matter for entitlement hearing on August 10 and 11, 2017 in Washington, D.C. Prehearing Order, ECF No. 64. On May 12, 2017, petitioners filed a motion to change the location of the entitlement hearing to Mobile, Alabama. Motion for Hearing Change of Location, ECF No. 65.

Following the undersigned's review of all of the evidence filed in this case in anticipation of the hearing, a status conference was held on May 30, 2017, to discuss petitioners' claim, Dr. Steinman's opinions that Heavenly's vaccines caused her medical condition and the absence of a claim for significant aggravation, in light of Heavenly's MRI revealing Dandy-Walker variant, and other congenital brain anomalies. Scheduling Order at 1, ECF No. 66.

On June 20, 2017, petitioners filed an Amended Petition to include a claim for significant aggravation. Am. Pet., ECF No. 69. That same day, the parties filed a joint status report requesting that the entitlement hearing be rescheduled to a later date to allow petitioners the opportunity to file an expert report addressing the significant aggravation claim. Joint Status Report, ECF No. 70. The entitlement hearing was rescheduled for June of 2018. Prehearing Order, ECF No. 73.

Petitioners filed a supplemental expert report from Dr. Steinman on November 21, 2017. Pet. Ex. 58, ECF No. 75. Petitioners filed updated medical records on April 12, 2018. Pet. Ex. 54-59, ECF No. 76.

An entitlement hearing was held in Mobile, AL, on June 18 and 19, 2018. *See* Scheduling Order at 1, ECF No. 88. Following the hearing, an Order was issued for the filing of additional evidence including but not limited to medical records referred to during the hearing that were not in the record and a supplemental expert report from Dr. Steinman. *Id*.; *see also* Pet. Ex. 66-67, ECF No. 97; Pet. Ex. 68-74, ECF No. 100.

On August 20, 2018, petitioner filed a compilation of photographs of Heavenly at birth from May of 2010, photographs reportedly from October of 2010, and photographs from November of 2010 and December of 2010. Pet. Ex. 62-65, ECF No. 92. Additional medical records were filed on October 15, 2018.

On January 2, 2019, petitioner filed a supplemental expert report from Dr. Steinman, Pet. Ex. 68, along with additional literature. Pet. Ex. 68-73, ECF No. 100.

The record was closed on March 1, 2019, and post-hearing briefs were ordered. *See* Scheduling Order at 1, ECF No. 104.

Post-hearing briefs were filed by both parties on June 14, 2019. ECF Nos. 113-14.

Unfortunately, petitioners' counsel advised on March 20, 2020 that Heavenly had passed away. ECF No. 115. Petitioners were ordered to file a copy of Heavenly's death certificate. Non-PDF Order, issued Apr. 6, 2020. On June 2, 2020, petitioners filed the death certificate, which did not contain the cause of death. Pet. Ex. 75, ECF No. 116. Petitioners were ordered to file documentation of Heavenly's cause of death. Scheduling Order, ECF No. 119. On October 26, 2020, petitioners filed updated medical records which revealed multiple hospitalizations, including Heavenly's final hospitalization in December of 2019 and her death on January 2, 2020. *See* Pet. Ex. 76, ECF No. 126.

This matter is now ripe for decision.

II. Issues to be Determined, Facts in Dispute, and Preliminary Statement

Petitioners initially alleged that the DTaP, Hib, IPV, and Prevnar vaccines administered to Heavenly on August 2, 2010 and September 28, 2010 were the cause-in-fact of her injury and developmental regression. An amended petition was filed and included allegations of significant aggravation. *See* Am. Pet. at 2. Ultimately, Dr. Steinman agreed with Dr. Holmes that Heavenly was born with a severe congenital cerebral malformation, referred to as Dandy-Walker variant, along with other congenital malformations. However, they disagreed as to the role these congenital malformations of the brain played in Heavenly's neurological disorder. Dr. Steinman opined that the combination of pertussis toxin and alum contained in the DTaP vaccines administered to Heavenly on August 2, 2010 and September 28, 2010 contributed to her neurological deficits, including developmental delay and seizures. Pet. Ex. 29 at 10; Tr. 161-62. Respondent postured that Heavenly suffered from congenital encephalopathy as a result of congenital brain malformation and cerebral dysgenesis, all occurring in utero, and the vaccines neither caused nor contributed to her current condition. Resp. Post-Hearing Brief at 12-13. The parties disputed that Heavenly "enjoyed normal development until August 2, 2010" or that the medical record

established that Heavenly "met certain developmental milestones prior to receipt of her August 2, 2010 vaccinations." Joint Submission at 2.

In an opening statement at hearing, petitioners' counsel stated that his preparation for hearing led him to believe that this matter would turn on the testimony of Ms. Martin and Ms. O'Quin, and "five or six records that need to be explained well to the Court to have you understand the history of this child. And I think that's what this case is going to be about." Tr. 4-5.

Respondent's counsel agreed, but added that, once flushed out, the facts would show that Heavenly's condition was not significantly aggravated by the vaccinations she received on August 2 and September 28, 2010. Tr. 7.

This case is more than simply understanding "five or six" records and the testimony of the caretakers; it is understanding the gravity of brain formation in utero, particularly the cerebellar vermis, which is located between the two hemispheres of the brain, the development of the connection between the hemispheres of the brain and the spinal cord, and the neurological and developmental impact when this area of the brain fails to develop. These events are borne out in *all* of the records between Heavenly's birth on May 26, 2010 and her first hospitalization in November of 2010. Notably, there were records that existed for Heavenly's medical care between June and September of 2010 that were not filed prior to hearing nor considered by the experts; these records included mandatory weight checks at the local Department of Health due to Heavenly's failure to thrive from birth onward.

Further, and perhaps the most important, is the medical record containing Heavenly's November 10, 2010 MRI at a little over five months of age. This MRI revealed that Heavenly was not only born with Dandy-Walker variant, which alone may have little effect, but that she was also born with other congenital brain malformations, including cerebral dysgenesis, vermian hypoplasia, diffuse cortical atrophy, and thinning of the corpus callosum, which resulted in microcephaly. These conditions, described in detail below, had a devastating impact on Heavenly's neurodevelopment in the first months of life.

There is no doubt petitioners, Ginger Martin and Catherine O'Quin, loved Heavenly deeply and had the best of intentions in caring for her. There is also no doubt that neither Ms. Martin nor Ms. O'Quin appreciated the gravity of the congenital brain anomalies with which Heavenly was born, or the effect those birth defects would have on Heavenly as she grew. It is with a heavy heart that I must rule against petitioners in this case, but it is my responsibility to apply the law without allowing emotions to dictate the outcome.

III. Dandy Walker malformations, the MRI of November 10, 2010, and the effect of these congenital brain abnormalities on neurodevelopment in the first months of life

A. Dandy-Walker malformations

Dandy-Walker complex "represents a group of developmental anomalies of the posterior fossa[6] that includes classic Dandy-Walker malformation, Dandy-Walker variant, and mega-

[6] The posterior fossa is the internal base of the skull, behind the temporal bones but in front of the transverse

cisterna magna." Pet. Ex. 38 at 1.[7] Classic Dandy-Walker malformation "is defined as a triad of cystic dilation of the fourth ventricle; complete or partial agenesis[8] of the cerebellar vermis; and an enlarged posterior fossa, with displacement of the tentorium and torcular and lateral sinus." *Id*. Dandy-Walker variant is characterized by "cerebellar dysgenesis,[9] without enlargement of the posterior fossa and with variable hypoplasia[10] of the cerebellar vermis. Ventricular dilatation may or may not be present. The cerebellar hemispheres may be small but morphologically normal." *Id*. "Mega-cisterna magna is defined as an enlarged cisterna magna with an intact cerebellar vermis and fourth ventricle. The cerebellum may be hypoplastic." *Id*.

Has et al. found that Dandy-Walker malformation and Dandy-Walker variant "show so many similarities that a clear-cut distinction is difficult" with "no significant difference in the spectrum of associated anomalies and postnatal prognosis between" the two. Resp. Ex. F at 1-2, 5.[11] The incidence of Dandy-Walker malformation is one out of 25,000 to 30,000; it is more common in females, and 44.8% of parents of fetuses with the malformation were consanguineous. *Id*. at 4.

Dandy-Walker disorders can be isolated to malformations of the posterior fossa and such disorders will have significantly better neurodevelopmental outcomes, but generally this is not the case. Resp. Ex. K at 1;[12] Resp. Ex. H at 2-3.[13] Agenesis of the corpus callosum,[14] cardiac

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sinuses; it is where the cerebellum, pons, and medulla oblongata rest. *Posterior cranial fossa*, STEDMAN'S MEDICAL DICTIONARY 350950, accessed via westlaw.com (last visited July 9, 2020) [hereinafter "STEDMAN'S"].

[7] Judy A. Estroff et al., *Dandy-Walker Variant: Prenatal Sonographic Features and Clinical Outcome*, 185 RADIOLOGY 755-58 (1992), filed as "Pet. Ex. 38" and "Resp. Ex. L."

[8] Agenesis means "absence or failure to form of any part." *Agenesis*, STEDMAN'S at 16460.

[9] Cerebellar dysgenesis means defective development of the cerebellum, a part of the brain. *Dysgenesis*, STEDMAN'S at 272440; *cerebellar*, *id*. at 162850; *cerebellum*, *id*. at 162940.

[10] Hypoplasia means underdevelopment of a tissue or organ, usually due to a decrease in the number of cells; atrophy due to destruction of some of the elements and not merely to their general reduction in size. *Hypoplasia*, STEDMAN'S at 429940.

[11] Recep Has et al., *Dandy-Walker Malformation: A Review of 78 Cases Diagnosed by Prenatal Sonography*, 19 FETAL DIAGN. THER. 342-47 (2004), filed as "Resp. Ex. F."

[12] I. Pascual-Castroviejo et al., *Dandy-Walker Malformation: Analysis of 38 Cases*, 7 CHILD'S NERV SYST. 88-97 (1991), filed as "Resp. Ex. K."

[13] N. Boddaert et al., *Intellectual Prognosis of the Dandy-Walker Malformation in Children: the Importance of Vermian Lobulation*, 45 NEURORADIOLOGY 320-24 (2003), filed as "Resp. Ex. H."

[14] The corpus callosum is an arched mass of white matter in the brain found in the depths of the longitudinal fissure, composed of three layers of fibers, the central layer consisting primary of transverse fibers connecting the central hemisphere. *Corpus*, DORLAND'S at 412; *callosum*, *id*.

malformations, and ventriculoseptal defects are the most common disorders associated with Dandy-Walker malformation. *Id*. at 6. The more anomalies associated with Dandy-Walker variant that are present, the worse the neurodevelopmental delay and prognosis. Resp. Ex. S at 7; *see also* Resp. Ex. Q at 4. Agenesis of the corpus callosum is frequently associated with low birth weight and poor prognosis. Resp. Ex. K at 7. The course of patients with Dandy-Walker malformation is "generally unsatisfactory." *Id*. at 8. Approximately three-quarters to 80% of patients are diagnosed before one year of age. *Id*. at 6-7.

"The cerebellar vermis forms in the 9th gestational week from midline fusion of the developing cerebellar hemispheres, beginning superiorly and continuing inferiorly, until the entire vermis is formed by the end of the 15th week" of gestation. Pet. Ex. 38 at 3; Resp. Ex. L at 3; *see also* Resp. Ex. F at 6 ("…the cerebellar vermis finishes its development from superior to inferior at about 17-18 weeks of gestation"); Resp. Ex. O at 4[15] ("The vermis…develops and becomes fully foliated by 4 months gestation"). Vermian hypoplasia is associated with major brain anomalies, most often agenesis of the corpus callosum. Resp. Ex. I at 2. The malformations of the posterior fossa and the associated anomalies suggest a teratogenic influence between the 4th and 7th embryonic weeks. Resp. Ex. K at 8.

"Neurodevelopmental delay has been reported in 40% to 60% of children with Dandy-Walker malformation, with the identification of additional anomalies leading to a worse prognosis." Resp. Ex. S at 7;[16] *see also* Resp. Ex. Q at 4[17] ("In studies where comparison of children with isolated DWM and those who had associated CNS anomalies was possible, we found that all children with DWM who were developing normally had no associated CNS malformations."). Vermian hypoplasia, which has an important role in neurodevelopment, has a wide range of developmental outcomes in children when it occurs in isolation. *Id*. When combined with posterior fossa anomalies, however, the outcome was "universally poor, with all [cases] having either abnormal neurodevelopmental outcome or death." *Id*. "These findings are similar to a previous report that risk for death increases significantly when additional anomalies are found in two or more organ systems." *Id*.

More recent literature notes that Dandy-Walker malformation "is diagnosed upon identification of vermis hypoplasia, rotation of the vermis away from the brain stem and an enlarged posterior fossa." Resp. Ex. T at 10.[18] Behavioral pathology can include motor deficits consistent with cerebellum damage, and, in 50% of patients, intellectual impairment tentatively correlated with the degree of loss of vermal lobulation. *Id*.

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[15] Melissa A. Parisi & William B. Dobyns, *Human Malformations of the Midbrain and Hindbrain: Review and Proposed Classification Scheme*, 80 MOL. GENET. METAB. 36-53 (2003), filed as "Resp. Ex. O."

[16] Kyla J. Patek et al., *Posterior Fossa Anomalies Diagnosed with Fetal MRI: Associated Anomalies and Neurodevelopmental Outcomes*, 32 PRENAT. DIAGN. 75-82 (2012), filed as "Resp. Ex. S."

[17] Marie-Eve Bolduc & Catherine Limperopoulos, *Neurodevelopmental Outcomes in Children with Cerebellar Malformations: A Systematic Review*, 51 DEV. MED. CHILD NEUROL. 256-67 (2009), filed as "Resp. Ex. Q."

[18] M. Albert Basson & Richard J. Wingate, *Congenital Hypoplasia of the Cerebellum: Developmental Causes and Behavioral Consequences*, 7 FRONT. NEUROANAT. 1-16 (2013), filed as "Resp. Ex. T."

Dandy-Walker variant is often under or undiagnosed on prenatal ultrasounds. Resp. Ex. F at 2. Studies dealing with posterior fossa anomalies like Dandy-Walker malformation, Dandy-Walker variant, and mega-cisterna magna stress the importance of fetal MRI in evaluating these disorders "as it provides detailed information about neuroanatomy and other malformations" that cannot be seen on level II ultrasound. Resp. Ex. S at 6-7.

B. Heavenly's November 10, 2010 MRI

A November 10, 2010 MRI performed on Heavenly at a little over five months old revealed "cystic enlargement of the posterior fossa which communicates the fourth ventricle" with vermian hypoplasia and diffuse cortical atrophy.[19] Pet. Ex. 4 at 118; Pet. Ex. 9 at 27. The impression was Dandy-Walker variant, cerebral dysgenesis, diffuse cortical atrophy, and thinning of the corpus callosum. *Id*. A later MRI showed "severe cortical and central atrophy with moderate ventriculomegaly" and "markedly delayed" myelination.[20] Pet. Ex. 10 at 24. Though Heavenly was initially microcephalic,[21] her subsequent MRI showed moderate ventriculomegaly,[22] which is found in 68% of Dandy-Walker malformation cases either before or after birth. Resp. Ex. N at 6;[23] Resp. Ex. O at 9.

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[19] Diffuse cortical atrophy is wasting away of the cells and tissue of the cortex, the outer layer of the brain. *Cortical*, DORLAND'S at 415; *atrophy*, *id.* at 172.

[20] Myelination begins prenatally at 30 weeks gestation. NELSON TEXTBOOK OF PEDIATRICS 27 (Robert M. Kliegman et al. eds., 19th ed. 2011) [hereinafter "NELSON'S"]. In full term infants, it is present by the time of birth in the dorsal brainstem, cerebral peduncles, and posterior limb of the internal capsule. *Id*. at 27-28. The cerebral white matter acquires myelin by one month of age and is well-myelinated by three months of age. *Id*. at 28. The subcortical white matter of the parietal, posterior, frontal, temporal, and calcarine cortex is partially myelinated by three months of age. *Id*. "Delayed" means postponement to a later time. *Delayed*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 476 (32d ed. 2012) [hereinafter "DORLAND'S"]. "Delayed myelination" means that myelination is occurring later than it originally would in development. In contrast, demyelination is the loss of the myelin sheath around a nerve fiber. *Demyelination*, STEDMAN'S at 235430; myelination; *myelination*, *id*. at 582200.

[21] Microcephalic means having microcephaly, which is abnormal smallness of the head. It is usually associated with intellectual disability. *Microcephalic*, STEDMAN'S at 551130; *microcephaly*, *id*. at 551160. Microcephaly is traditionally defined as a head circumference two or more standard deviations lower than the mean for age and gender. SWAIMAN'S PEDIATRIC NEUROLOGY E-BOOK: PRINCIPLES AND PRACTICE 208 (6th ed. 2017). Severe microcephaly is three or four standard deviations lower than the mean. *Id*.

[22] Ventriculomegaly is a condition in which the ventricles of the brain become larger than normal. This can occur when cerebrospinal fluid becomes trapped in the ventricles. Ventricles develop early in pregnancy, at about the 15th week. *Ventriculomegaly*, BOSTON CHILDREN'S HOSPITAL, http://www.childrenshospital.org/conditions-and-treatments/conditions/v/ventriculomegaly (last visited July 9, 2020).

[23] Francesco D'Antonio et al., *Systematic Review and Meta-Analysis of Isolated Posterior Fossa Malformations on Prenatal Imaging (Part 2): Neurodevelopmental Outcome*, 48 ULTRASOUND OBSTET. GYNECOL. 28-37 (2016), filed as "Resp. Ex. N."

C. Normal Growth and Development

The development of normal gross motor, fine motor, communication and language skills, and cognitive development is necessary in order to differentiate between reaching milestones and regression of milestones. In medical terms, regression is a return to a former or earlier state. *Regression*, DORLAND'S at 1595. In layman's terms, regression is a reversion to an earlier mental or behavioral level. MERRIAM WEBSTER'S DICTIONARY at 419. By either definition, a regression means that one has acquired or attained a skill or level that is then lost. Succinctly, there cannot be a regression of milestones if one has not yet attained those milestones.

NELSON'S provides the milestones for normal development: at one-and-a-half months, an infant smiles in response to a face or voice; at two months, she can hold her head steady while sitting and stares momentarily at a spot where an object disappeared; at three months, she can pull herself to sitting without head lag and bring her hands together at the midline; at three-and-a-half months, she can grasp a rattle; at four months, her asymmetric tonic neck reflex and palmar grasp are gone, and she can inspect her hands at midline, reach for objects, voluntarily release objects, and stare at her own hand; at five-and-a-half months, she can transfer an object from one hand to the other; at six months, she can sit without support and has monosyllabic babble; at six-and-a-half months, she can roll from her back to her stomach; and at eight months, she can grasp her finger to her thumb. *Id*. at 27.

A chart of emerging patterns of behavior in the first year of life contains the following, with only the first four months of life highlighted for purposes of this decision: at one month, an infant has head lag when she is pulled to sitting, will watch a person and follow moving objects, has body movements in cadence with the voices of others, and begins to smile; at two months, she raises her head slightly, has head lag when she is pulled to sitting, follows a moving object to 180 degrees, smiles with social contact, listens to voices, and coos; at three months, she lifts her head and chest with arms extended when prone, reaches toward and misses objects, waves at toys, demonstrates early head control with bobbing and a rounded back, makes defensive movements or selective withdrawal reactions, has sustained social interaction, listens to music, says "aah" and "ngah," and no longer has a Moro response; and at four months, she lifts her head and chest when prone, brings her hands to her midline, reaches and grasps objects and brings them to her mouth, has no head lag when she is pulled to sitting, sees a pellet but makes no move to reach it, laughs out loud, may show displeasure if social context is broken, and is excited to see food. NELSON'S at 28.

As the medical records reflect, and as detailed by respondent's experts below, Heavenly never reached her two- and four-month milestones; therefore, she could not have lost them. Ms. Martin knew this, as clearly admitted during her testimony at hearing and set forth below.

IV. Legal Framework

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that he or she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed."

Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Alternatively, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii)(II). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[24]

To prove causation, petitioners must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination the vaccinee received caused the vaccinee's injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each of the *Althen* prongs requires a different showing. Under the first *Althen* prong, petitioner must provide a "reputable medical theory" demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id*. at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Secretary of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

[24] The Vaccine Act also requires petitioners to show by preponderant evidence the vaccine suffered from the "residual effects or complications" of the alleged vaccine-related injury for more than six months, died from the alleged vaccine-related injury, or required inpatient hospitalization and surgical intervention as a result of the alleged vaccine-related injury. § 11(c)(1)(D). It is undisputed that this requirement is satisfied in this case.

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs*., 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id*. at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

The third *Althen* prong requires that petitioner establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id*. However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id*.; *see also Locane v. Sec'y of Health & Human Servs*., 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

A petitioner may also be eligible for compensation if he or she had a preexisting condition which was significantly aggravated by a vaccine. *See* § 11(c)(1)(C). In considering a significant aggravation claim for an on-Table injury, the Federal Circuit placed the most significance on whether petitioner's symptoms began within the time period proscribed. *Whitecotton v. Sec'y of Health & Human Servs*., 81 F.3d 1099, 1107 (Fed. Cir. 1996) ("Instead of asking whether the person's symptoms would have occurred absent the vaccine, our test hovers close to the statutory mandate, and relieves a petitioner of the burden of proving causation if she can show that the first symptom or manifestation of the significant aggravation of her condition occurred within the table time period provided in the statute.")

For a significant aggravation claim for an off-Table injury, the petitioner's burden is raised, requiring petitioner to show, by preponderant evidence, proof of

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving ex rel. Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009). The fourth, fifth, and sixth factors are derived from *Althen* prongs one, two, and three, respectively. *Id*. The Federal Circuit has agreed with this approach. *See W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) ("We hold that the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims.") Due to the requirement to prove causation, one special master has recommended evaluating "the last three *Loving* factors first." *Hennessey v. Sec'y of Health & Human Servs*., No. 01–190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009), *mot. for rev. denied*, 41 Fed. Cl. 126 (2010).

However, the third *Loving* factor, determining whether the person suffered a "significant aggravation" of his or her condition, leads to the question of what constitutes a significant aggravation. Based on the legislative history and the language of the statute, it appears that Congress intended for a "significant aggravation" of a condition to present rather dramatically. *See* H.R. Rep. 908, 99th Cong.2d Sess. 1, reprinted in 1986 USCCAN 6287, 6356 ("This [significant aggravation] provision does not include compensation for conditions which might legitimately be described as preexisting (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis" (emphasis added)); *see also* 42 U.S.C. § 300aa-33(4) ("The term "significant aggravation" means any change for the worse in a preexisting condition which results in *markedly greater* disability, pain, or illness accompanied by *substantial deterioration* of health" (emphases added)).

In *Sharpe*, the Federal Circuit clarified the *Loving* factors and what is required by petitioners to successfully demonstrate an off-Table significant aggravation claim. *Sharpe v. Sec'y of Health & Human Servs*., 964 F.3d 1072 (Fed. Cir. 2020), *filed for panel rehearing*, No. 19-1951 (Fed. Cir. Sept. 8, 2020). *Loving* factor three "only requires a comparison of a petitioner's current, post-vaccination condition with her pre-existing pre-vaccination condition." *Sharpe*, 964 F.3d at 1082; *Whitecotton*, 81 F.3d at 1107. A petitioner is not required to demonstrate an expected outcome or that their post-vaccination condition was worse than such an expected outcome. *Sharpe*, 964 F.3d at 1082.

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Id*. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948). But petitioners can support their claim with oral testimony if it is credible and consistent with the medical records. *See, e.g.*, *Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a

fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). In short, "the record as a whole" must be considered. § 13(a).

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 973 (Fed. Cir. 2011). Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). And nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Finally, although this decision discusses many but not all of the literature in detail which was submitted by the parties, the undersigned reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

V. Summary of Relevant Facts

A. Heavenly's Medical History

1. Medical History Prior to the First Vaccinations – Birth to August 2, 2010.

Heavenly was born at River Oaks Hospital on May 26, 2010 at 38 weeks gestation by cesarean section due to failure to progress.[25] *See generally* Pet. Ex. 2; Pet. Ex. 21 at 24. She

[25] Heavenly's mother was 17 years old with special needs. Heavenly's father was unknown. Pet. Ex. 21 at 6. At an OB/GYN appointment on December 3, 2009, Heavenly's mother checked "yes" for the use of "medications (including supplements, vitamins, herbs or OTC drugs)/illicit/recreational drugs/alcohol since last menstrual period." *Id*. at 7. The pregnancy was otherwise uneventful.

weighed six pounds, 12 ounces and was 19 inches long with a head circumference of 33 cm.[26] Pet. Ex. 2 at 4, 6. She was noted to be in the 25th percentile for weight and length and in the 50th percentile for head circumference. *Id*. at 49. APGAR scores were nine at one minute and nine at five minutes. *Id*. at 6. Screening tests by the Mississippi Department of Health were within normal limits. *Id*. at 19. Heavenly received a hepatitis B vaccination on May 26, 2010 in her left thigh. *Id*. at 24.

Heavenly was "[B]reast feeding well" but losing weight. She lost two ounces on May 27, 2010, four ounces on May 28, 2010, and four ounces on May 29, 2010, for a total loss of ten ounces. Pet. Ex. 2 at 9, 36, 40. On May 29, 2010 at 8:45 am, she was noted to be jaundiced; her bilirubin level was high, at 10.2. *Id*. at 15, 47. Later that day, Heavenly was discharged home with her mother with instructions to return with Heavenly in two days for a weight check. She was also instructed to follow up with a pediatrician in two weeks. *Id*. at 13, 47. Heavenly weighed six pounds, two ounces upon discharge. *Id*. at 9, 40.

On June 8, 2010, Heavenly was presented for her first pediatric visit to Gulf Shores Pediatrics ("Gulf Shores") for noted "wheezing." Pet. Ex. 3 at 25. Heavenly was 13 days old and noted as a "well newborn." *Id*. She weighed seven pounds, one ounce and was breastfed. *Id*.

On June 28, 2010, Heavenly was presented to Gulf Shores for a one-month well checkup. Pet. Ex. 3 at 24. She weighed 7 pounds, 10 ounces with head circumference of 35.5 cm. *Id*. She was noted to be in the 10-25th percentile for weight and the 25th percentile for head circumference.[27] *Id*. A hepatitis B vaccine was delayed by her family until the next visit. *Id*.

On July 22, 2010, Heavenly was presented to Baldwin County Health Department ("Baldwin") for a weight check by her mother and grandmother. Pet. Ex. 67 at 2. She was reported to be six pounds, 12 ounces at birth but her discharge weight was unknown. *Id*. On July 22, 2010, she weighed seven pounds, 13 ounces. *Id*. Heavenly's mother was breastfeeding every three hours but was having difficulty keeping Heavenly latched to her breast. *Id*. A football hold was suggested and "worked a lot better." *Id*. Heavenly weighed eight pounds after feeding. *Id*. Breastfeeding "on demand" in one to two-hour intervals was advised with a return visit scheduled for Monday, July 26, 2010 for weight check. *Id*. At eight weeks old, Heavenly was 20.5 inches long and weighed seven pounds, eight ounces; she was now in the 2nd percentile for length and 10th percentile for weight. *Id*. at 4. Her head circumference was not measured.

On July 26, 2010, Heavenly was presented to Baldwin for a weight check. Pet. Ex. 67 at 2. She had not gained weight or grown in length. *Id*. at 2, 4. Her mother was pumping four to five ounces per day; she was advised to continue pumping and feeding pumped milk. *Id*. at 2. She was instructed to return for a weight check on August 2, 2010. *Id*.

On August 2, 2010, Heavenly was presented to Baldwin for a weight check. Pet. Ex. 67 at 2. She had been taking pumped milk but was provided eight ounces of Similac per day. *Id*. Her mother wanted to continue to use formula and breast milk. *Id*. Four cans of Similac were provided.

[26] Heavenly's head circumference was noted in another record as 34 cm. Pet. Ex. 2 at 9.

[27] This is a drop of 25 percentage points in head circumference in the first month of life.

Id. She was instructed to return in a month. *Id*. At ten weeks of age, Heavenly weighed eight pounds and was still 20.5 inches long. *Id*. at 2, 4. She was in the 2nd percentile for weight and length. *Id*. at 4. Her head circumference was not measured. *Id*.

That same day, August 2, 2010, Heavenly was presented to Gulf Shores for a two-month well checkup. Pet. Ex. 3 at 23. She was breast and bottle fed with formula as a supplement. *Id*. The two-month developmental portion of the record was not filled out, but the physical examination was noted as normal. *Id*. At a little over two months of age, Heavenly weighed eight pounds, five ounces and was 21 inches long, with a head circumference of 37.75 cm. *Id*. She was in the 3rd percentile for weight, 5th percentile for length, and 25th percentile for head circumference. *Id*. She was documented with poor weight gain. Her mother was instructed to return with Heavenly in two weeks for a weight check. *Id*. Pentacel (DTaP, Hib, and polio), Prevnar, and rotavirus vaccines were given. *Id*.

2. Heavenly's Medical History Following the First Set of Vaccinations on August 2, 2010 and Before the Second Set on September 28, 2010.

Heavenly was next presented to Gulf Shores on August 16, 2010. A "Sick Visit Form"[28] documented a two-and-half-month-old infant in for a "weight check." Pet. Ex. 3 at 22. She weighed eight pounds, 11 ounces and was taking four ounces of formula every two hours. *Id*. She was reported as going for more than one day without a bowel movement, but had soft stools with no blood, was not gassy, and slept all day. *Id*. Upon examination, Heavenly was slender, alert, and comfortable. *Id*. She had a protruding abdomen.[29] *Id*. The assessment was poor weight gain. *Id*. Blood work and urinalysis were ordered at this visit. Urinalysis was noted as "clear." *Id*. Blood work revealed Heavenly to be anemic and malnourished. *Id*.; Pet. Ex. 6 at 1-2 (Lab results reflecting a high white blood cell count, low red blood cell count, low levels of hemoglobin, hematocrit, and total protein, high platelet, lymphocyte, neutrophil, and eosinophil levels, high glucose level, low globulin level, and high SGOT/AST levels). Heavenly's caretakers were advised that if she did not gain weight, further workup with hospitalization would be considered. *Id*. Any reduction in energy level should be reported immediately. *Id*.

Heavenly was returned to Gulf Shores on August 27, 2010 for a weight check. Pet. Ex. 3 at 21. She weighed nine pounds, six ounces. *Id*. She was given a second hepatitis B vaccine. *Id*.

On September 2, 2010, Heavenly was presented to Baldwin for a weight check. Pet. Ex. 67 at 3, 5. She was being fed cereal and 22 to 28 ounces of Similac per day. *Id*. at 3. Similac Advanced Powder was provided. *Id*. at 3, 5. At 14 weeks old, Heavenly weighed nine pounds, six ounces, and was 22 inches long; she was in the 2nd percentile for weight and the 8th percentile for length. *Id*. at 4. Her head circumference was not measured. *Id*.

On September 10, 2010, Heavenly was returned to Gulf Shores for a weight check. Pet.

[28] It appears that a "sick visit form" is used to document anything other than a well-baby check-up. This occurs throughout the Gulf Shores records.

[29] The pediatrician's notes are handwritten and illegible in many places throughout the Gulf Shores records filed as Pet. Ex. 3.

Ex. 3 at 21. She weighed ten pounds, three ounces, and was noted to be very gassy; a history of milk allergy in the family was reported. *Id*. Her formula was changed from Similac to Isomil. *Id*. She remained on Isomil thereafter. Pet. Ex. 67 at 5.

On September 20, 2010, Heavenly was presented to Gulf Shores for a three-month well baby checkup. Pet. Ex. 3 at 20. Her grandfather was in the hospital with shingles, but she had not been around him. *Id*. She weighed 11 pounds. *Id*. On physical examination, Heavenly was sleepy but would rouse, had a red bumpy rash in the diaper area but was otherwise normal. *Id*. The assessment on that date was diaper rash; Nystatin was prescribed. *Id*.

On September 23, 2010, Heavenly's mother called Gulf Shores to advise that the Nystatin burned when used; Lotrimin was suggested instead. Pet. Ex. 3 at 20. Heavenly's mother reported that the rash was slightly raised and looked like an allergy rash. *Id*.

On September 24, 2010, Heavenly was presented to Gulf Shores for a "Sick Visit," with continued rash on her bottom; Lotrimin was not working. Pet. Ex. 3 at 19. She weighed 11 pounds, four ounces and had five scabbed bumps on her chest, abdomen, and back, with nothing in her diaper area. *Id*. She also had some dry patches. *Id*. The assessment was "viral exanthem ? ectopic ?" which would resolve. *Id*. The pediatrician added an asterisk at the top of the page writing "unable to get Heavenly to focus on face, [grandma] says she does focus [at] home, watches TV." *Id*.

On September 28, 2010, Heavenly was presented to Gulf Shores for her four-month well-child checkup. Pet. Ex. 3 at 18. She weighed 11 pounds, five ounces and was 23.25 inches long with a head circumference of 38.5 cm. *Id*. She was in the 10th percentile for weight, 25th percentile for length, and 3rd percentile for head circumference. *Id*. She did not meet the developmental milestones for a four-month-old; "babbles; laughs; prone, raises body on hands; rolls stomach to back; holds own hands, grasps rattles; and reaches for and bats objects." *Id*. She did meet "smiles" and "opens hands." *Id*. She "maybe" recognized her parents' voice and touch. *Id*. The assessment was well, small, developmentally behind, with questionable vision. *Id*. She was referred to an ophthalmologist, Dr. Rich; an appointment was scheduled for 2:00 pm on October 15, 2010. *Id*. Heavenly received Pentacel, Prevnar, and rotavirus vaccines at that visit. *Id*.

3. Heavenly's Medical History Following the September 28, 2010 Vaccinations and thereafter.

Four days later, on October 1, 2010, Ms. Martin called Gulf Shores, reporting concern for Heavenly's development; she was not reaching for things, did not seem to recognize people and was not tracking. Pet. Ex. 3 at 17. No other complaints were made. The record notation was to have her vision screened, "then go from there – per KCL – is behind in developmental (sic) about 1 mo." *Id*.

On October 15, 2010, Heavenly was presented to Dr. Rich at Vision Partners. Pet. Ex. 5 at 15. The grandmother reported that the pediatrician sent them because Heavenly was "not following all that well w/her eyes," and that Heavenly's mother had a learning disability. *Id*. Dr. Rich examined Heavenly noting she was oriented with normal mood and affect, but she "did not follow

left." *Id*. His impression was "small but normal." *Id*. at 16.

On October 18, 2010, the family was notified by Gulf Shores that referrals had been made for Heavenly to be seen at University of South Alabama ("USA") for Genetics and Neurology. Pet. Ex. 3 at 17. A neurology appointment was scheduled for 2:00 pm on April 13, 2011. *Id*. Ms. Martin advised the caller that she was putting Heavenly in an infrared sauna to get the mercury from the vaccines out of her body. *Id*. Ms. Martin was instructed to stop and was informed that mercury had not been used in vaccines since 2001. *Id*.

In an October 20, 2010, phone call to Gulf Shores it was reported that Heavenly had "problems with constipation – hard stools and juices no help on Similac…." Pet. Ex. 3 at 16. Lactulose was suggested. *Id*. No other complaints were made.

The Gulf Shore records reflect that on October 21, 2010, the appointments with the geneticist and neurologist were moved up to November 9, 2010 and January 12, 2011, respectively. Pet. Ex. 3 at 16.

On November 1, 2010, Heavenly was presented to Gulf Shores for a weight check. Pet. Ex. 3 at 15. She weighed 12 pounds, 11 ounces, was 24.25 inches long, with a head circumference of 39.5 cm. *Id*. She was in the 25th percentile for length and the 3rd percentile for head circumference. *Id*. The Lactulose reportedly caused abdominal cramping and Miralax was suggested. *Id*. No other complaints were reported.

On November 3, 2010, Ms. Martin again called Gulf Shores due to constipation with very hard stool. Pet. Ex. 3 at 15. The nurse documented the record that Heavenly could be heard screaming in the background. *Id*. Miralax was to be continued. *Id*. A green glycerin suppository was prescribed. *Id*. No other complaints were made. *Id*.

On November 9, 2010, Heavenly was presented to Dr. Jose Martinez, a clinical geneticist, "because of history of developmental delay and microcephaly." Pet. Ex. 7 at 1. Dr. Martinez wrote, "We understand that she has been having abnormal developmental progress, and she was recently seen in the eye clinic and found to have a number of abnormalities of concern including the fact that she was not following light and the family was told that she needed to be seen by a neurologist." *Id*. Physical examination on that date revealed "a hypotonic child who does not follow and who appears microcephalic with a head circumference of 40 cm and a closed anterior fontanel."[30] *Id*. Her pupillary response was "very sluggish." *Id*. She had "an abnormal posture with extension response and a very lethargic appearance." *Id*. Her height and weight were in the 25th percentile. *Id*. She did not have dysmorphic features or typical manifestations of a recognizable syndrome. *Id*. Dr. Martinez contacted Dr. Lovlie at Gulf Shores and Dr. Maertens in neurology at USA Hospitals. It was determined that Heavenly should be admitted to the hospital for a complete neurological workup. *Id*.

Upon admission at USA Hospitals, Heavenly came under the care of Dr. Maertens, a

[30] The anterior fontanel, also called the "soft spot," is the junction where the two frontal and two parietal bones meet. *Fontanelle,* DORLAND'S at 727; *fonticulus anterior, id*. The anterior fontal is typically closed by 12 months of age. SWAIMAN'S at 14.

pediatric neurologist, for "developmental delay with microcephaly." *See generally* Pet. Ex. 4. She was a five-month-old with a history of feeding difficulties, developmental delay, and failure to consistently meet developmental milestones. Pet. Ex. 4 at 4. She was seen by Dr. Rich for concerns of blindness. Dr. Rich referred her to Dr. Martinez for suspected genetic abnormality and developmental delay. *Id.* at 9. Dr. Martinez documented microcephaly, poor feeding, developmental delay, and suspected genetic or metabolic abnormality or cerebral palsy. *Id*. On examination she exhibited head lag, could not roll over, did not push up when prone, could not sit up unsupported, and could not hold her head up while sitting supported. *Id*. She did not track or follow objects, turn in response to noise, or readily hold objects. *Id*. She lived with her mother, great-grandmother, grandmother, and grandfather. *Id*. The family reported that Heavenly's mother was mentally retarded with an estimated level of functioning of eight years old. *Id*. The family history was positive for diabetes and asthma. *Id*. Heavenly's height and weight were in the 5th percentile and her head circumference "a little below the 5th percentile." *Id*.

An MRI performed on November 10, 2010 revealed "cystic enlargement of the posterior fossa which communicates the fourth ventricle. There is [vermian] hypoplasia. There is diffuse cortical atrophy… The corpus callosum is thinned." Pet. Ex. 4 at 118; Pet. Ex. 9 at 27. The impression was Dandy-Walker variant, diffuse cortical atrophy, and thinning of the corpus callosum. *Id*. Heavenly was noted to have periods of apnea during the MRI and was placed in the PICU overnight; after having no further events, she was transferred out of the PICU. *Id*. at 4. A chest x-ray was clear. *Id*. at 119. An EEG performed on November 11, 2010 revealed "epileptic activity arising from the posterior (rear) region [of the brain], interictally." Pet. Ex. 9 at 48. Keppra was started. Pet. Ex. 4 at 7. A second EEG on November 12, 2010, showed continued seizure spikes. Pet. Ex. 8 at 61, 107. Topamax was added to Keppra. *Id*.; Pet. Ex. 4 at 7. A lumbar puncture was performed and revealed an elevated concentration of lactate. *Id*. at 47. "Elevated CSF lactate may be due to inborn errors of metabolism affecting gluconeogenesis, pyruvate dehydrogenase complex, the Krebs cycle, and the mitochondrial electron transports chain." *Id*.

A third EEG performed on November 15, 2010, showed improvement of seizure activity. Pet. Ex. 8 at 62. Seizure activity was noted as "much more prominent on the right than the left and consist[ed] of poly spikes and slow waves on the right." *Id*. at 62-63, 108-09; Pet. Ex. 9 at 45-46. The epileptic activity on the left was "less frequent with longer periods of seizure freedom [were] seen," and could last up to 10 seconds. *Id*. at 63, 109. There was still no photic driving response. *Id*. The assessment was "microcephaly most likely due to Dandy-Walker variant, cortical atrophy and corpus callosum thinning, as per MRI." Pet. Ex. 9 at 23. Genetic and other testing was pending at discharge. Pet. Ex. 4 at 7.

In the discharge summary dated November 15, 2010, Heavenly was documented as a five-month-old with feeding difficulty and developmental delay, admitted for consistently failing to meet developmental milestones. Pet. Ex. 4 at 4; Pet. Ex. 9 at 24. She was hypotonic with no following vision but had 2+ reflexes and was moving all extremities well. *Id*. The discharge diagnoses were microcephaly, developmental delay, seizure disorder, and cerebral dysgenesis. *Id*.

Extensive genetic and other testing over time ruled out many genetic abnormalities. Pet. Ex. 7 at 4-5; Pet. Ex. 8 at 40-41, 45, 53, 58-60, 83-86, 96, 138-39; Pet. Ex. 9 at 20-22.

On November 22, 2010, Heavenly was presented to Dr. Maertens for follow up.[31] Pet. Ex. 8 at 14, 26, 76-78, 129, 134, 137. He documented that the MRI "showed severe atrophy of the brain involving both the cerebrum and the cerebellum with a very small cerebellar vermis and large space around the cerebrum and cerebellum. White matter was very small with a very thin corpus callosum." *Id*. His impression was seizures, hydrocephalus, and cerebral palsy, which appeared to be progressive, as Heavenly had a normal head size at birth but at six months old, had a head circumference of 40.3 cm, equal to that of a three-and-a-half to four-month-old. *Id*. at 15, 130, 135. Another EEG was needed to assess seizure control; Dr. Maertens also wanted to schedule additional genetic testing. *Id*. Other testing indicated that a mitochondrial disease was less likely. *Id*. Heavenly was to continue on Topamax. *Id*.

On December 2, 2010, Heavenly was presented to Baldwin for a weight check. Pet. Ex. 67 at 2. Her neurologic issues and care were noted. She was reported to have "60% of normal brain size." *Id*. At six months old, Heavenly weighed 13 pounds, eight ounces, and was 25.4 inches long; she was in the 8th percentile in weight. *Id*. at 4. Her head circumference was not measured.

On December 3, 2010, Heavenly was presented to Gulf Shores for a six-month well-baby visit. Pet. Ex. 3 at 14. She was fed formula, apples, and bananas, no vegetables and was constipated *Id*. A follow-up was planned with a gastroenterologist. *Id*. She did not meet any of the six-month developmental milestones. *Id*. She was to follow up with neurology, early intervention, and WIC. *Id*. She weighed 13 pounds, three ounces, was 24.75 inches long, and had a head circumference of 39.75 cm. *Id*. Her weight was in the 10th percentile, her height was in the 25th percentile, and her head circumference was in the 5th percentile. *Id*. She was noted to have developmental delay. Her physical examination was otherwise normal. *Id*. Vaccinations were to wait, pending neurological examination. *Id*.

On December 13, 2010, Heavenly was presented to Dr. Maertens. Pet. Ex. 8 at 24. She had "not been acting well." *Id*. Videotapes of her seizures were provided. *Id*. She was referred for monitoring and was to continue with Topamax. *Id*.

Skin and muscle biopsies performed on January 7, 2011, showed minimal pathologic change, no fibrosis, myositis or vasculitis. Pet. Ex. 4 at 122, 128, 130-32. An EEG performed on January 11, 2011 was "markedly abnormal due to multifocal epileptic activity, which [was] more prominent over the posterior region, and occasional attenuation of the background in generalized fashion with fast activity occurring after arousal." Pet. Ex. 8 at 57, 102. "This feature is somewhat reminiscent of what one sees in infantile spasms or Lennox-Gastaut syndrome and treatment with Felbatol or Vigabatrin may be considered." *Id*.

Heavenly remained under the care of Dr. Maertens for seizures and microcephaly. On January 25, 2011, Dr. Maertens documented that Heavenly was not being given her seizure medications. Pet. Ex. 8 at 22, 72. She was eight months old; weighed 14 pounds, ten ounces, with a head circumference was 39 cm. *Id*. The impression was microcephaly and mitochondrial encephalopathy. *Id*.

[31] Though the medical records appear to indicate that Dr. Paul Maren was the treating physician, it was Dr. Maertens who conducted and documented the examinations.

Later that day, Ms. Martin telephoned Gulf Shores to report they had seen Dr. Maertens earlier that day and still was no definite diagnosis, but "possibly microencephalopathy." Pet. Ex. 3 at 11. Ms. Martin stated "no pertussis vaccine or flu vaccine, wants immunization given at ½ doses…" *Id*. A sleep study was ordered for episodes of blue around her mouth and snoring. *Id*. at 8, 10-11.

In a February 16, 2011 record Dr. Martinez wrote testing showed "encephalopathy associated with brain atrophy as revealed on imaging studies." Pet. Ex. 7 at 2; Pet. Ex. 8 at 56, 101.

A February 17, 2011 visit with Dr. Maertens, noted Heavenly as 15 pounds, eight ounces, kicking more, jerked "a lot," was not rolling over and had poor head control. Pet. Ex. 8 at 20-21, 70-71. His impression was mitochondrial encephalopathy/microcephaly. *Id*. at 20, 70.

Further genetic testing could not rule out the possibility of interference with precursor RNA processing or confirm or exclude mitochondrial respiratory chain disorder. Pet. Ex. 8 at 38, 52, 81-82, 95.

Dr. Rich continued to follow Heavenly, noting on March 25, 2011, that she was "more alert" and "look[ed] around more." Pet. Ex. 5 at 11. She was gaining weight. *Id*. Upon examination, she did not follow faces or light. *Id*.

At an April 19, 2011 visit, Dr. Maertens documented questionable mitochondrial epilepsy. Pet. Ex. 8 at 18. Physical and occupational therapy were ordered, as was another EEG, coenzyme Q10, and testing to rule out Angelman Syndrome. *Id*.

Heavenly had some progress with strength, mobility, and range of motion in physical therapy. Pet. Ex. 8 at 119.

On April 28, 2011, Heavenly was eleven months old; she weighed 16 pounds and was 28 inches long and described as small with decreased tone. Pet. Ex. 3 at 6. She was diagnosed with asthma and prescribed albuterol. *Id*. Later that day, Ms. Martin telephoned Gulf Shores to report that Heavenly "screamed all the way home from todays (sic) visit and for two more hours. Body was rigid, screamed with clenched fists. Totally unconsolable (sic), will hold off on further [nebulizer] treatments until tomorrow A.M., will await instructions from [Dr. Lovlie] as she believes it was [nebulizer] treatment that caused this Reaction (sic)." *Id*.

At her one year old check up on June 1, 2011, Heavenly weighed 16 pounds, one ounce and was 29 inches long, with a head circumference of 41 cm. Pet. Ex. 3 at 5. She was in the 3rd percentile for weight and head circumference but the 50th percentile for length. *Id*. She was noted as small and delayed, and her eyes did not focus. *Id*. The assessment was cerebral dysgenesis, microcephaly, and development delay. *Id*. Vaccines were refused. *Id*.

On October 10, 2011, Heavenly was presented to Dr. Weldon Mauney, a neurologist at the Child Neurology Center of Northwest Florida ("Child Neurology") for a second opinion. Pet. Ex. 10 at 25. The family reported, "No problems until after 4 mo shots." *Id*. at 32. Dr. Mauney

documented:[32]

> Patient has a history of severe regression of her developmental milestones noticed around the age of 4 months, parents emphasize that this was noticed after her four-month immunization shots….3 days after her immunizations at 4 months of age patient was noticed with decreased activity, she was no longer tracking, she was no longer reaching out for objects, developed poor head control. Patient was subsequently admitted in 10/2010 to the Children's and Woman's Hospital in Mobile Alabama for further evaluation and treatment. Diagnosed then with seizures, central hypotonia, microcephaly…The neurology notes that I have available describe the findings on MRI which shows severe atrophy of the brain involving both cerebrum and cerebellum with a small cerebellar vermis and a thin corpus callosum. An EEG performed on November 15, 2010 describes a slow and attenuated background, poly-spikes and slow waves were seen originating from the occipital head regions subclinical electrographic activity was described. Patient was then started on Keppra which was discontinued due to apparent issues with the taste of the medication. She was then started on Topamax which was discontinued by the family in January of this year. The family states that after starting Topamax they have seen worsening of her condition and for that reason it was discontinued. In November 2010 she presented one event of rhythmic jerking of the left hand which was captured on video, they also captured one event consisting of jerking of the left lower extremity. Once or twice a week she is noticed to have brief events described as "zigzagging" where she appears to extend the side of her body and flex the other side for a few seconds…Patient is described in some of the notes to have a mitochondrial encephalopathy. The parents were trying to make arrangements to see a mitochondrial specialist in Atlanta Georgia.

Id. at 25. Heavenly's mother's learning disability was noted. *Id*. Dr. Mauney noted that Heavenly drank from a bottle, smiled, kicked her legs, and would occasionally orient to sound and bring her hands to midline but could not sit unsupported, roll, or recognize facial expressions. *Id*. at 26. Upon examination, he found her to be awake and alert with no dysmorphic features. *Id*. She had extension posturing on occasion, mainly when stimulated. *Id*. She did not blink to threat or light. *Id*. She had decreased axial tone, poor head control with significant head lag, resistance in the upper and lower extremities, decreased overall tone, and brisk deep tendon reflexes in her knees. *Id*. She had increased tone at the ankles. *Id*. Her pupils were round and slow to react to light. *Id*. His initial impression was metabolic disorder; he ordered an EEG and brain MRI and planned to refer Heavenly to a neurogenetics center in Atlanta. *Id*. He instructed the family to follow-up in the clinic in two months. *Id*.

A 19-channel EEG performed on October 18, 2011 was abnormal "due to the presence of attenuated slow background, due to the presence of sharp waves as well as spike and slow wave

[32] Though not highlighted here in detail, Heavenly was under the care of multiple specialists for a host of medical issues, including but not limited to gastroenterology, urology, nutrition, orthopedics, physical and occupational therapy, swallowing issues with multiple hospitalizations, and ultimate G-tube placement due to gastric bleeds. This is in no way meant to minimize what this child suffered, but simply to focus on the issues key to determining entitlement.

over the bilateral occipital head regions and intermittent focal slowing." Pet. Ex. 66 at 7. The findings were "consistent with a diffuse bi-hemispheric cerebral dysfunction with potential areas of epileptogenic tendencies over the bilateral occipital head regions." *Id*.

MRI of the brain on November 10, 2011 without contrast revealed severe atrophy and delayed myelination. Pet. Ex. 10 at 24.

At a December 5, 2011 visit with Dr. Mauney, Heavenly was documented to have microcephaly, a history of global developmental delays, and encephalopathy of unknown origin. Pet. Ex. 10 at 22. She had "[s]teadily been making improvements" in tracking, smiling, head control, sounds, and reaching for objects but could not sit unsupported. *Id*. The family denied seizure activity but reported brief jerking movements when tired. *Id*. She slept a lot, but when awake, was alert and energetic. *Id*. She had occasional constipation. *Id*. Urine tests were normal. *Id*. A kidney ultrasound was pending. *Id*.

On December 15, 2011, Heavenly underwent EEG testing with video. Pet. Ex. 20 at 23; Pet. Ex. 66 at 8. The findings were abnormal and "consistent with a diffuse bi-hemispheric cerebral dysfunction as well as associated potential areas of focal cortical disturbance with possible epileptogenic tendencies over the occipital and frontal polar head regions." *Id*.

On January 4, 2012, Dr. Mauney again documented encephalopathy of unknown etiology. Pet. Ex. 10 at 16. A recent sleep study revealed "central apneas which were not clinically significant." *Id*. No seizures or regression in milestones were noted. *Id*. Long-term EEG findings were discussed with the family. *Id*. at 17. Additional testing was ordered. *Id*.

On March 6, 2012, Heavenly returned to Dr. Mauney. Pet. Ex. 10 at 14. The record notes that the grandmother had obtained full custody. *Id*. Also reported was an episode with "a couple of minutes" of unresponsiveness lasting 20 to 30 seconds with "no apparent postictal state," and "an increase in the random brief jerking movements." *Id*. She was reported to be more interactive; smiling more, opening and closing her hands and had improved head control. *Id*. She had been reaching out for objects but not holding them. *Id*. She was tolerating a pureed diet without choking, only occasional drooling. *Id*. However, she also had intermittent episodes of screaming where she appeared to be in pain and distress and was poorly consolable; these episodes improved with Motrin and were infrequent. *Id*. There were no issues with sleeping. *Id*. Recent lab work was normal. *Id*. Dr. Mauney recommended proceeding with the barium swallow test. *Id*. at 15. He discussed the episodes of myoclonic jerks and staring events with her grandmother, as well as the potential complications of untreated seizures. *Id*. "The grandmother is not willing to treat her with antiepileptic medications at this time" but the possibility of a ketogenic diet was discussed. *Id*. Dr. Mauney recommended an evaluation at the University of Alabama at Birmingham ("UAB"). *Id*.

On May 11, 2012, Heavenly was returned to Dr. Mauney for intermittent episodes of discomfort, irritability, and screaming, during which she appeared to be in pain. Pet. Ex. 10 at 12. Her grandmother believed the events were weather-related. *Id*. She reportedly was taken to the emergency room four days prior and given Tylenol with codeine, with no effect. *Id*. She had mild jerking of her hands lately. *Id*. Upon examination, Heavenly was awake, with no apparent eye contact; she did not blink to threat but would blink to light. *Id*. She had a good range of motion

throughout and tone appeared slightly increased in the lower extremities. *Id*. She had poor head control and was unable to sit unsupported. *Id*. Dr. Mauney discussed the possibility of headaches and prescribed Periactin; if that did not work, they would try Topamax. *Id*. at 13.

At a visit on October 22, 2012, Dr. Mauney wrote, "There has been no clear cause for her encephalopathy." Pet. Ex. 10 at 10. She was making progress with motor skills in therapy, was more awake and alert, was smiling, more focal, supporting her weight, had improved head control, and was able to feed with a spoon but was still on a pureed diet. *Id.* She had recently been diagnosed with hip displacement on the left and was followed by orthopedics. *Id*.

An EEG on October 30, 2012, was abnormal "due to the presence of a poorly sustained 5 Hz background" and "frequent sharp waves over the bilateral occipital head regions." Pet. Ex. 10 at 9; Pet. Ex. 20 at 26; Pet. Ex. 66 at 10. The findings were again noted to be potentially "consistent with a diffuse bihemispheric cerebral dysfunction as well as more focal areas of cortical dysfunction or structural abnormality over the bilateral occipital head regions." *Id.*

On December 4, 2012, Heavenly was presented to Dr. Mauney with improvement with physical and occupational therapy; she was able to raise her arms, was vocalizing more, was more alert, and had improved eye contact. Pet. Ex. 10 at 7. She was awake, alert, and smiling, and had increased tone and improvement in range of motion. *Id*. Her pupils were equal and reactive to light. *Id*. Her hands were mostly fisted, but she could open them. *Id*. She exhibited brisk bicep and knee reflexes. *Id*.

Dr. Mauney's impression at this point was "encephalopathy of unknown etiology although suspected due to DPT immunization." Pet. Ex. 10 at 2; Pet. Ex. 20 at 52. The plan was to continue current interventions and do a repeat MRI and EEG. *Id*.

Heavenly's EEGs continued to show abnormality "due to the presence of infrequent sharp waves and intermittent focal slowing over the left occipital head region, this (sic) may indicate a potential cortical structure abnormality with epileptogenic tendencies." Pet. Ex. 24 at 1; Pet. Ex. 66 at 11.

MRIs showed "[m]arked volume loss [in the] cerebral hemispheres and, to a lesser extent, cerebellar hemispheres, consistent with the earlier study." Pet. Ex. 24 at 2. There was "[p]rogression of myelination of the periventricular white matter. Elsewhere, white matter signal characteristics remain abnormal with T2 prolongation, likely gliosis." *Id*.

In 2014, Dr. Mauney prescribed Klonopin for seizures. Pet. Ex. 24 at 9. The family discontinued it due interference with eating and drowsiness. *Id*. She continued to have brief myoclonic jerks. *Id*. Dr. Mauney recommended testing for SCN1A. *Id*.

Heavenly was hospitalized for pneumonia, laparoscopic Nissen fundoplication, and Stamm gastrostomy, failure to thrive, anemia, malnutrition, and gastric bleeds. *See generally*, Pet. Ex. 25; Pet. Ex. 55; Pet. Ex. 56; Pet Ex. 59; Pet. Ex. 65; Pet. Ex. 66.

Heavenly suffered multiple upper respiratory infections in the fall and winter of 2019 and

passed away on January 2, 2020. Pet. Ex. 75 at 1; Pet. Ex. 76 at 39, 619, 656, 661, 670.

B. Affidavits and Testimony of the Petitioners, Ginger Martin and Catherine O'Quin.

1. Affidavits and Testimony of Ginger Martin

Ginger Martin is Heavenly's great-aunt. Pet. Ex. 28 at 1. Ms. Martin and Ms. O'Quin are sisters and the appointed legal guardians for Heavenly. ECF No. 78 at 1.

Ms. Martin affirmed "[s]ince receiving [the allegedly causal] vaccinations, Heavenly has been developmentally delayed, suffers from seizures and related ailments. She has been diagnosed with encephalopathy associated with brain atrophy. Physicians have related this condition to a reaction from her 2010 vaccinations." ECF No. 1-2 at 2.

Ms. Martin was not present for any prenatal visits with Heavenly. She lived five to six hours away. Tr. 11. She was present for Heavenly's birth on May 26, 2010 and photographed it. Tr. 12; ECF No. 78 at 1. She described Heavenly as alert, strong, and "looking at the lights." Tr. 13. She had an APGAR score of 9 and slight jaundice. ECF No. 78 at 1. Following the birth, Heavenly, her mother, and Ms. O'Quin lived with Ms. Martin and her late husband, Tim. Tr. 13-14. Ms. Martin went to every doctor's visit except one. Tr. 16. She further stated she, Ms. O'Quin, Tim, and maybe Heavenly's mother went to every pediatric visit; Tim did not go when he had shingles. Tr. 37, 39.

At 13 days old, Heavenly was examined by Dr. Lovlie, who said she was strong and healthy, with just a little wheeze. Tr. 17; Pet. Ex. 3 at 25. No concerns about her development were raised. Tr. 17.

On June 28, 2010, Heavenly had a one-month old checkup; there were no concerns noted. Tr. 18; Pet. Ex. 3 at 24. "She was a healthy, beautiful baby." Tr. 18.

Ms. Martin affirmed prior to August 2, 2010, Heavenly would grasp Tim's finger, looked at him when he spoke to her, followed Ms. Martin's finger with her eyes when Ms. Martin read to her, tried to pull up, and reached for toys and mobiles. ECF No. 78 at 1.

At her nine-week check-up on August 2, 2010, there were no concerns. Tr. 19. Formula was added because Heavenly was not gaining weight. Tr. 19-20; ECF No. 78 at 2; Pet. Ex. 3 at 23. Heavenly "received her vaccinations at this time in spite of any concerns of lack of weight gain." ECF No. 78 at 2.

Ms. Martin affirmed after Heavenly received DTaP, Hib, IPV and Prevnar vaccinations on August 2, 2010, she cried a lot, slept much more than normal, and started having trouble suckling. ECF No. 1-2 at 1; ECF No. 78 at 2. "She lost her focus and alertness. She would not reach for things." ECF No. 1-2 at 1. "I called the pediatrician and took Heavenly back in for evaluation of our concerns. The pediatrician said Heavenly was just being lazy." ECF No. 78 at 2.

At hearing, Ms. Martin testified Heavenly was not irritable and did not have a fever

between August 2 and August 16, 2010. She only slept more. Tr. 28-29. She further stated Heavenly would no longer hold a rattle, follow her finger, reach for things, or coo, but Ms. Martin did not recall when during this two-week period Heavenly stopped engaging in these behaviors. Tr. 22-23, 47. She stated she had pictures of Heavenly doing these activities, but the camera was stolen. Tr. 47. Ms. Martin agreed during that two-week period she did not contact any medical professional to report any concerns with Heavenly's behavior. Tr. 29.

Ms. Martin stated that on August 16, 2010, she took Heavenly to the pediatrician due to her concern that Heavenly was sleeping all day, and no longer reaching for things or responding. Tr. 21-22; Pet. Ex. 3 at 22. She stated that Heavenly slept 18 hours a day and was not as alert or interested in the things she was before. Tr. 24-27. She agreed Heavenly could still be aroused. Tr. 29. She agreed that blood work was ordered at the August 16 visit. Tr. 31-32. Ms. Martin disagreed that the August 16 appointment was a scheduled visit for weight check, stating that her weight would have been checked by the health department and adding that Heavenly went to "a lot of weight checks" at the health department.[33] Tr. 23-24.

Ms. Martin then stated that on August 27, 2010, she took Heavenly to the pediatrician for a weight check and a hepatitis B vaccine, which was received without event. Tr. 32-33. Ms. Martin agreed that she did not mention any of the concerns she was testifying about to the pediatrician at that visit. Tr. 33; Pet. Ex. 3 at 21.

Ms. Martin agreed that at the September 20, 2010 pediatric visit, she advised the pediatrician that Heavenly was gassy and she was concerned about a milk allergy. Tr. 33, 35. She did not recall any other discussions or concerns discussed at this visit. Tr. 33-35; Pet. Ex. 3 at 21. She then stated that she constantly complained to the pediatrician about Heavenly sleeping a lot, not being as alert, and not doing "the things that she was supposed to be doing." Tr. 36-37; Pet. Ex. 3 at 21. She agreed that Heavenly had a diaper rash and was sleepy but could be aroused. Tr. 37-38; Pet. Ex. 3 at 20.

Ms. Martin affirmed, "By September 24, 2010 I was calling the doctor's office expressing my concerns about [Heavenly]'s continued decrease in focus and worsening of other symptoms." ECF No. 78 at 2. However, at hearing Ms. Martin agreed it was Dr. Lovlie who said she could not get Heavenly to focus at that visit and that she responded Heavenly watched TV at home. Tr. 41-42. Ms. Martin clarified references in the record to "GM" were to Ginger Martin. "I'm the one in the family that people expect to keep up with everything." Tr. 41-42; Pet. Ex. 3 at 20.

Ms. Martin affirmed that the September 28, 2010 pediatric visit was for concerns over Heavenly's weight, but she was given the DTaP, HIB, IPV and Prevnar vaccines, "in spite of our growing concern over [Heavenly]'s lack of response to stimuli, weakened suckle when taking her bottle, as well as decreased strength in her limbs." ECF No. 78 at 2. She further affirmed that after her vaccinations on that day, Heavenly screamed a lot. *Id.*

Ms. Martin conceded at hearing that it was apparent to her by September 28, 2010, and

[33] This is when it was learned that Heavenly had been taken to the Baldwin County Health Department for weight checks; records of these weight checks had not been filed in this case or considered by the experts in this matter.

from her conversations with Dr. Lovlie, that something was wrong with Heavenly. Tr. 55-59. Heavenly was not pulling herself up or rolling over. Tr. 45. She had not met any of the milestones listed on the pediatrician's developmental chart for four months of age. Tr. 49-51. Ms. Martin confirmed that Heavenly received her vaccinations after her physical examination on September 28, 2010. Tr. 43-44. Ms. Martin agreed that the referral to Dr. Rich, an eye specialist, was because Dr. Lovlie could not get Heavenly to focus. Tr. 44-45; Pet. Ex. 3 at 18. Ms. Martin then stated that she did not recall vaccinations being given at this visit. Tr. 52.

Ms. Martin testified that, after the September 28, 2010 pediatric visit, Ms. O'Quin, Heavenly, and Heavenly's mother went to Mississippi to get their belongings because they had decided to move to Alabama. Tr. 52-53. Ms. Martin stated that she heard Heavenly crying in the background every time she spoke to Ms. O'Quin on the phone and recalled being told that Heavenly could not be consoled and "she's not eating like she was." Tr. 60-62.

Ms. Martin affirmed that she next saw Heavenly on October 1, 2010, at which time she claimed Heavenly's arms would fall back, "she had no reaction to things she used to react to, and no recognition of anything." ECF No. 78 at 2. Ms. Martin affirmed that she "immediately" called the pediatrician to express her concerns that the vaccines had adversely affected Heavenly. *Id.*

However, at hearing, Ms. Martin stated that, upon her return from Mississippi, Heavenly was "floppy," but Ms. Martin did not think either Ms. O'Quin or Heavenly's mother noticed, and she did not contact a doctor or take Heavenly to a doctor or an emergency room. Tr. 62-64.

Ms. Martin stated that on October 1, 2010, she called the pediatrician to report that Heavenly was "just limp, she wasn't raising her arms up. She wasn't alert like she was. She – she was real weak." Tr. 65. When it was pointed out to Ms. Martin that the record did not reflect any of those complaints, only the concerns that had previously been raised by Dr. Lovlie to Ms. Martin, Ms. Martin stated that she did not think Dr. Lovlie appreciated the gravity of the situation because she scheduled an appointment with a geneticist, when Heavenly needed a neurologist. Tr. 65-67, 82. The visits were not until April and it was October, but Dr. Lovlie said you have to follow the steps, eye doctor, geneticist, neurologist. Tr. 82-83. Ms. Martin agreed that Dr. Lovlie was looking for a genetic disorder because Heavenly's mother had problems, but Ms. Martin felt that none of that fit. Tr. 83-84; ECF No. 78 at 3.

Ms. Martin affirmed that Heavenly was seen by Dr. Rich, an eye specialist, on October 15, 2010, and Dr. Rich advised them that Heavenly had "a chemical reaction of some kind." ECF No. 78 at 2. She further affirmed that Dr. Rich called the pediatrician and explained that Heavenly "needed to see a neurologist right away." *Id.*

At hearing, Ms. Martin testified that Dr. Rich "was concerned about the vaccine…he was the first one that seemed to recognize that that could happen." Tr. 69. When it was pointed out to Ms. Martin that there was no reference to any recent vaccinations in Dr. Rich's medical record, she stated, "…you know, we did discuss that day about the vaccine." She then recited a conversation she claimed to have heard between Dr. Rich and Dr. Lovlie by phone. Tr. 69-71. Dr. Rich's record was read to Ms. Martin, which included his impression that Heavenly was oriented to time and place, with a normal examination. Tr. 71-72. Ms. Martin then conceded that she really

could not hear Dr. Rich's conversation with Dr. Lovlie, only that Heavenly needed to see a neurologist. Tr. 72-74.

Ms. Martin was questioned about the use of infrared light on Heavenly as documented in Dr. Lovlie's record of October 18, 2010. *See* Pet. Ex. 3 at 17. Ms. Martin stated, "My late husband had progressive viral encephalopathy... And I had researched and found that the infrared saunas were real good at healing…so I had a big infrared sauna that we had purchased to have at the house for him…they're really good for detoxing." Tr. 75-76. "Someone" told her the vaccines were to blame for Heavenly's condition and she thought that the infrared sauna would "help get the mercury out of her body." Tr. 77, 80.

Ms. Martin conceded that her phone call to Dr. Lovlie on October 20, 2010 was to report Heavenly's constipation. Tr. 88; Pet. Ex. 3 at 16. She further agreed that she took Heavenly to Dr. Lovlie on November 1, 2010 for constipation. Tr. 89-90. She testified, "[W]e knew something was wrong with Heavenly" at this visit. Tr. 90-91. Dr. Lovlie's office had rescheduled appointments for November 9, 2010 for the geneticist and January 12, 2011 for the neurologist. Tr. 88-89. There was nothing they could do but wait for the specialists; "you just have to follow the steps." Tr. 82-83, 90-95.

Ms. Martin stated that she and Ms. O'Quin took Heavenly to Dr. Martinez the geneticist on November 9, 2010. He examined Heavenly and sent them to the emergency room. Tr. 96-97; Pet. Ex. 7 at 1. All genetic testing was negative. ECF No. 78 at 2.

Ms. Martin affirmed that Heavenly "was diagnosed as having encephalopathy associated with brain atrophy. Physicians have related this condition to a reaction from her 2010 vaccinations." ECF No. 78 at 3. She further affirmed that the neurologist showed his students "how floppy [Heavenly] was and explained that it was a chemical reaction." *Id*. at 2-3.

However, at hearing, Ms. Martin stated that, when the neurologist saw Heavenly in the emergency room, she and Ms. O'Quin were separated, and Tim was called to find out "what [they] had done" to Heavenly. Tr. 97. Ms. Martin stated that she knew from fostering children when a child comes to the emergency room "and they look like they have an injury" the doctors "will separate everybody and say: What happened?" Tr. 102-03. She stated that Tim told them nothing had happened to Heavenly. Tr. 103-04. She added that social services visited them several times because Heavenly was so small and having problems.[34] Tr. 104. Ms. Martin confirmed that she provided all the medical history and the paperwork at the hospital. Tr. 104-05.

A portion of the hospital record was read to Ms. Martin: "End of July, would not hold head up, (flopping) had no use of hands. The only thing that she held in hand was candy bar, (was not even aware of it). According to uncle, he thinks symptoms started four months ago." Tr. 109-10, quoting Pet. Ex. 4 at 12. Ms. Martin confirmed that "uncle" referred to Tim but insisted they only asked Tim "if he knew what had happened to her, if we had had anything bad done to her." Tr. 108. It was explained to Ms. Martin that the record was from the attending neurologist documenting his telephone conversation with Tim. Tr. 109-10. Ms. Martin admitted that Tim was very involved with the care of Heavenly every day, but he has since passed away, so there was no

[34] The records from social services were not filed in this matter.

way to ask him about the conversation with the doctor. Tr. 110-11.

Ms. Martin was questioned about the collage of pictures she created that was filed as Pet. Ex. 54. Tr. 111. She admitted to having corrected the "red eye" on the June 23, 2010 picture of Heavenly being held by Tim. Tr. 114-15. She did not recall if she corrected the eyes on page two of Heavenly in the striped jumper but agreed that the picture looked overcorrected. Tr. 115-16.

Ms. Martin denied being told by any medical professional that there was concern for Heavenly's head circumference, that her head was not growing between the time she was born in May until her hospitalization in November, or that she was microcephalic. Tr. 51-52, 116-17. She recalled Heavenly's vision being discussed. Tr. 55. She recalled being told that Heavenly was falling behind but does not recall when that was. Tr. 55-56.

2. Affidavit and Testimony of Catherine J. O'Quin

Ms. O'Quin submitted an affidavit filed on July 18, 2013 that simply affirmed that she read Ms. Martin's "affidavit and concurs with the statements contained therein." ECF No. 1-1.

It is noted that neither Ms. Martin nor Ms. O'Quin were present when the other was testifying.

Ms. O'Quin adopted her son's daughter, Heavenly's mother, when she was two-and-half years old. Tr. 122-23. During her pregnancy, Heavenly's mother lived in Mississippi with Ms. O'Quin. Tr. 120. Ms. O'Quin went to all prenatal visits; there were no issues during the pregnancy. Tr. 119-20. Ms. O'Quinn was present at the hospital when Heavenly was born. Tr. 121. Heavenly's "birth score was a 10. They downgraded it to a 9 because she got jaundice. But, other than that, she was perfect." Tr. 121. Ms. Martin and Ms. O'Quin are sisters. Tr. 122. Heavenly's mother and Ms. O'Quin went to Alabama to live with Ms. Martin and Tim when Heavenly was three or four days old. Tr. 122-23. They lived with Ms. Martin and Tim for six months until they got their own place in Alabama. Tr. 123-24. Ms. O'Quin, Ms. Martin, and Tim were Heavenly's caretakers. Tr. 129.

Ms. O'Quin stated she went to every pediatric visit except one. Tr. 124. The first visit was at two weeks old; Heavenly was back to her birth weight and meeting "her points." Tr. 124. Ms. O'Quin could not recall each doctor's visit, but stated she was present at the two-month visit when Heavenly received her first vaccines. Tr. 125. "She cried, just like any other normal child would cry." Tr. 125. Ms. O'Quin did not recall Dr. Lovlie expressing any concerns about Heavenly at that visit. Tr. 125-26.

Ms. O'Quin testified that Heavenly was "perfect" during the first two months of life. She tried to hold her bottle, was aware of things around her, and would follow Ms. Martin's finger when she read to her. Tr. 128-29. However, with further questioning, Ms. O'Quin admitted she had no memory of the details of the first two months of Heavenly's life or if Heavenly was gaining weight. Tr. 130-32. She did recall giving Heavenly formula because her mother's milk dried up. Tr. 131.

Ms. O'Quin testified that after the first set of vaccinations, Heavenly slept all day and even into the night but "[t]hen when she would wake up, she would be awake for like 24 hours." Tr. 126, 132. Ms. O'Quin added, "I'm not really sure of what the timeline would have been. I just remember her sleeping a lot and then being awake for long periods of time." Tr. 127. She added when Heavenly was awake, she was active. "Sometimes she really was active. She would, you know, watch the little swinging toys." Tr. 133. Even when Heavenly slept a lot, "[y]ou could stick the bottle in and she'd take it when she'd be sound asleep." Tr. 135-36.

Ms. O'Quin recalled that Heavenly "became very, very constipated" about a week after the first set of vaccinations," and Ms. Martin called the doctor about it. Tr. 133-34. She further recalled taking Heavenly frequently to the health department to have her weight and iron levels checked. Tr. 134-35.

Ms. O'Quin recounted how Heavenly did not like being on her belly between the two- and four-month vaccinations, "she would rather be on her back so she could see what was going on." Tr. 141-42. Ms. O'Quin testified she would talk to Heavenly, and Heavenly would look at her and appear to be paying attention, but she could not control her head very well. Tr. 132. When Ms. O'Quin played "how big" with Heavenly, which she still does, Heavenly would react. Tr. 142-43. According to Ms. O'Quin, Heavenly became "*more* floppy" after her four-month vaccinations adding "to me, all newborns are kind of floppy because they haven't learned to control their movements." Tr. 143.

According to Ms. O'Quin after Heavenly received her four-month vaccinations, she took Heavenly's mother and Heavenly back to Mississippi to get some clothes and see some friends. Tr. 136. About two or three days after the vaccinations, Heavenly "started just…crying and crying. Nothing you could do would console her." Tr. 137. By the time they returned to Alabama, Heavenly had stopped crying but "didn't act the same." Tr. 137. She was a "floppy baby" and "didn't really have control…of her head like she did." Tr. 137. Then they went to Dr. Rich, who said that Heavenly could not see; she used to watch TV, but "got to where she really didn't." Tr. 140.

Ms. O'Quin remembered Ms. Martin calling the doctor when they got back to Alabama but did not recall what was said. Tr. 138. She went to the visit with Dr. Rich, who said that Heavenly needed a neurologist. Tr. 138. She recalled the geneticist also saying Heavenly needed a neurologist and admitting her to the hospital. Tr. 139. She recalled the neurologist in the hospital trying to figure out what was wrong with Heavenly and doing a lot of tests. Tr. 139-40.

She did not recall Dr. Lovlie ever saying that Heavenly was developmentally delayed. Tr. 140-41.

The hospital record of the attending neurologist's conversation with Tim was read to Ms. O'Quin. When asked if Tim was accurate that Heavenly's floppiness started at the end of July, Ms. O'Quin responded, "If Tim was here, whatever he would say would be the truth. Because he was very active with Heavenly." Tr. 144.

VI. Analysis

Because this is not a Table case and petitioners are required to present a plausible medical theory demonstrating how the DTaP vaccine could cause or significantly aggravate Dandy-Walker variant, it is logical to evaluate the last three factors of *Loving*, which are also the three prongs of *Althen*, first. *See Hennessey*, 2009 WL 1709053, at *42.

A. *Althen* Prong 1/*Loving* Factor 4: Reputable Medical Theory

1. Dr. Steinman's Opinion

Starting from a position that children with Dandy-Walker variant can be normal, Dr. Steinman proposed two theories involving the components of the DTaP vaccine and the aluminum adjuvant as the cause or significant aggravation of the severity of Heavenly's condition and her brain anomalies.[35] By way of overview, Dr. Steinman's theories involved causes of neuronal death. First, pertussis toxin, from which the acellular pertussis component of the DTaP vaccine derives, causes ADP-ribosylation, a process involved in neuronal death. To support this opinion, Dr. Steinman discussed the ability of IL-1β, a cytokine, to cause seizures. *See* Pet. Ex. 34; Pet. Ex. 52; Pet. Ex. 55. Dr. Steinman further proposed that the aluminum adjuvant in the DTaP vaccine induces the secretion of IL-1β, which in turn triggers the immune system to produce inflammasomes; a mutation in NACHT, a component of the inflammasome, has for example been linked to CINCA/NOMID, a pediatric neurological disease which admittedly Heavenly did not have. *See* Pet. Ex. 29 at 8-9.

In support of the first part of his theory, Dr. Steinman submitted an excerpt from the CDC's Pink Book to show that pertussis vaccine can cause seizures and neurologic damage. *See generally* Pet. Ex. 31.[36] He added that the CDC recognizes seizures, hypotonic-hyporesponsive episodes, and other manifestations of an encephalopathic state to occur with the acellular pertussis vaccine, though at a lower rate when compared to the whole cell pertussis vaccine. Tr. 181-82; Pet. Ex. 29 at 7; Pet. Ex. 31 at 15. Whole-cell pertussis vaccine contains 3,000 different proteins, while the acellular pertussis vaccine contains two to five proteins; for this reason, there is less chance of seizures, encephalopathy, and hypotensive episodes with DTaP as compared to the whole-cell vaccine. Pet. Ex. 73 at 2.[37]

According to Dr. Steinman, since pertussis toxin, a key component of the acellular pertussis

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[35] As respondent pointed out in his post-hearing brief, "Dr. Steinman opine[d] that the combination of pertussis toxin and alum in the DTaP vaccine contributed to [Heavenly]'s neurological deficits, including developmental delay and seizures…. Accordingly, petitioners have abandoned their argument that the Hib, polio and Prevnar vaccines caused-in-fact or significantly aggravated [Heavenly]'s neurological condition." Resp. Post-Hearing Brief at 11 n.5.

[36] *Pertussis*, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 261-78 (13th ed. 2015), filed as "Pet. Ex. 31."

[37] Mahendra K. Patel et al., *Diphtheria, Pertussis (Whooping Cough), and Tetanus Vaccine Induced Recurrent Seizures and Acute Encephalopathy in a Pediatric Patient: Possibly Due to Pertussis Fraction*, 3 J. PHARMACOL. PHARMACOTHER. 71-73 (2012), filed as "Pet. Ex. 73."

vaccine, causes ADP-ribosylation, which plays a role in seizures and neuronal death, pertussis toxin therefore causes neuronal death. Tr. 217; Pet. Ex. 29 at 7-8. Another set of enzymes, the poly-ADP-ribose polymerases ("PARPs"), catalyze the polymerization of ADP-ribose moieties and are also associated with neuronal death in a variety of neurodegenerative diseases. *Id*. Dr. Steinman relied on the Baram study, which discussed interleukin-1 beta ("IL-1β") triggering seizures, stating that IL-1β is "a major chemical that's triggered by the pertussis vaccine." Tr. 185-86; Pet. Ex. 60.[38] Dr. Baram's article did not discuss ADP-ribosylation.

Dr. Steinman submitted one of his own studies, which involved a mutation in the inflammasome involving a cryopyrin, caspase-1, to show that unregulated activity can result in increased IL-1β activity and the role it may play in Alzheimer's disease and other autoimmune brain diseases, such as MS. "Fever, triggered via the cytokine interleukin-1, IL-1, is the quintessential manifestation of the brain's reaction to an immune danger signal. IL-1 also mediates a group of rare autoimmune diseases of the brain. Fever, of course, is the most common manifestation of a fundamental interaction between the brain and the immune system." Pet. Ex. 32 at 2.[39] Dr. Steinman testified that the DTaP vaccine was the danger signal; although Heavenly did not have a fever within 72 hours of either set of vaccinations, the CDC Pink Book states that convulsions can occur with or without fever. Tr. 215-16; Pet. Ex. 29 at 9-10; Pet. Ex. 32 at 2; Pet. Ex. 61 at 2.[40]

For the second part of the theory, Dr. Steinman opined that alum, the adjuvant used in the DTaP vaccine, "is known to induce the secretion of IL-1β, a master regulator of innate immunity." Pet. Ex. 29 at 8. Alum can trigger inflammasomes, "inducing an influx of inflammatory cells and triggering the cytokine IL-1β associated with vaccine reactions, seizures and neurodegeneration." *Id*. Unlike the adaptive immune system, the innate immune system makes a "powerful and quick response to danger," dealing with the most urgent problem "without tailoring a specific receptor to neutralize the danger signal in the form of antigen." *Id*. The innate immune system will trigger a toll-like receptor ("TLR") in response to an infectious microbe or a vaccine. *Id*. Additionally, the innate immune system has a cytosolic[41] system to sense danger, the NOD-like receptor ("NLR"). *Id*. The inflammasome is where the TLR system and NLR system are integrated, with IL-1β being the "major currency" of the inflammasome. *Id*. "The core of the inflammasome contains a pyrin domain, a caspase recruitment domain (CARD), and an intermediary nucleotide-binding domain (NBD; NACHT or NAD); and a C-terminal LRR (leucine-rich repeat). Mutations in the NACHT domain of NALP3 are linked to CINC/NOMID, a pediatric neurological disease. Manifestations of CINCA/NOMID begin in the neonatal period." *Id*. Clinical manifestations of CINCA/NOMID

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[38] Annamaria Vezzani and Tallie Z. Baram, *New Roles for Interleukin-1 Beta in the Mechanisms of Epilepsy*, 7 EPILEPSY CURR. 45-50 (2007), filed as "Pet. Ex. 60."

[39] Roopa Bhat and Lawrence Steinman, *Innate and Adaptive Autoimmunity Directed to the Central Nervous System*, 64 NEURON 123-32 (2009), filed as "Pet. Ex. 32."

[40] Andrey M. Mazarati, *Cytokines: A Link Between Fever and Seizures*, 5 EPILEPSY CURR. 169-70 (2005), filed as "Pet. Ex. 61."

[41] "Cytosolic" refers to the fluid components of the cytoplasm, exclusive of other components of the cell, like mitochondria, the endoplasmic reticulum, and other membranous and particulate components. *Cytosolic*, STEDMAN'S at 227350; *cytosol*, *id*. at 227340.

include urticaria, skin rashes, hives, fever, and recurrent meningitis. *Id*. "Elevated intracranial pressure, hearing loss, seizures, and delayed and impaired neurological development ensue." *Id*. Visual loss occurs from increased intracranial pressure which leads to brain atrophy. *Id*. at 8-9. Dr. Steinman conceded Heavenly did not have NOMID/CINCA, but he relied on the study to show that "activation of the inflammasome is associated with neurodegenerative disease." *Id*. at 9; Pet. Ex. 32 at 4.

Dr. Steinman submitted a 2008 letter published in NATURE, Pet. Ex. 37[42] to show that Nalp3 is a crucial element of aluminum adjuvants, or "alum" and that alum "may induce inflammasome activation through membrane disruption." Pet. Ex. 37 at 1, 3. However, the testing was done on baby mice, who lacked Nalp3, for purposes of designing effective but safe adjuvants in the future. *Id*. Dr. Steinman referenced to the excerpt from the CDC's Pink Book, which discussed Boosterix and Daptacel, formulations of Tdap for ages 10 and older which contain alum adjuvants. Pet. Ex. 31 at 8. Dr. Steinman also relied on an article[43] which discusses the history of alum[44] and its effects on the body, and concluded that, although "[a]luminum adjuvants have been successfully used in hundreds of millions of humans since 1932, greatly decreasing morbidity and mortality with minimal toxicity" further research is necessary to improve "the effectiveness of aluminum salts and speed the development of alternative adjuvants." Pet. Ex. 43 at 6.

In Dr. Steinman's opinion, the combination of the pertussis toxin and alum in the DTaP vaccine "contributed to Heavenly's neurological deficits including developmental delay and seizures." Pet. Ex. 29 at 10. The components of the DTaP vaccine, particularly pertussis toxin and alum, have the capacity to induce necrosis in neurons. *Id*. Though conceding that it is unknown whether the pertussis toxin destroys specific cells or all cells in the brain, Dr. Steinman opined it is "likely to be killing the most vulnerable cells." Tr. 218. He admitted that "Most of the information, of course, has been worked out in rodents. And the susceptibility of different parts of a rodent's brain are going to be different than a human brain." Tr. 218.

2. Dr. Holmes's Opinion

Dr. Holmes deferred to Dr. McGeady for Prong I but agreed that pertussis vaccine has been reported to cause encephalopathy within 72 hours of the vaccine. However, he was unaware of the attenuated, or acellular, pertussis vaccine being capable of causing brain injury to the extent alleged in this case. Tr. 295.

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[42] Stephanie C. Eisenbarth et al., *Crucial Role for the Nalp3 Inflammasome in the Immunostimulatory Properties of Aluminum Adjuvants*, 453 NATURE 1122-27 (2008), filed as "Pet. Ex. 37."

[43] Philippa Marrack et al., *Towards an Understanding of the Adjuvant Action of Aluminum*, 9 NAT. REV. IMMUNOL. 287-93 (2009), filed as "Pet. Ex. 43."

[44] Alum refers to any double salt formed by a combination of a sulfate of aluminum, iron, manganese, chromium, or gallium with a sulfate of lithium, sodium, potassium, ammonium, cesium, or rubidium. In immunology, alum is sometimes used as an adjuvant, or a vehicle used to enhance antigenicity. *Alum*, STEDMAN'S at 25310; *adjuvant*, *id*. at 13380.

3. Dr. McGeady's Opinion

In addressing part one of Dr. Steinman's theory, Dr. McGeady credited Dr. Steinman with an eloquent description of how ADP-ribosylase activity could activate inflammasomes, but he did not agree with Dr. Steinman's theory. "He put it together as nicely as one can. I am not aware of this having actually happened. And I certainly don't think it happened in this case." Tr. 332-33. Dr. McGeady disagreed with Dr. Steinman's proposition that, because pertussis toxin is an ADP-ribosylate that can cause neuronal death, the acellular pertussis toxoid in the DTaP vaccine can also cause neuronal death.

Dr. McGeady explained that the Black study, relied on by Dr. Steinman and in which he was involved, set out to create a non-toxic vaccine by impacting a *Bordetella pertussis* organism to create a toxin that retained some of the properties of pertussis toxin, without the toxicity of the ADP-ribosylation. Tr. 321-22; Pet. Ex. 33.[45] A 99% decrease in toxicity as measured by ADP-ribosylation was achieved, but it lost some of the immunoprotective properties. Tr. 322. The Black paper infers that "if you get rid of the toxicity, you're decreasing the immunogenicity, too." Tr. 322. Dr. McGeady agreed that "the detoxified pertussis toxin in the acellular [DTaP] vaccine still contains some toxin activity" but pointed out that the Black study did not examine the acellular DTaP vaccine. Tr. 322-23.

Dr. McGeady addressed other studies involving ADP-ribosylase as the cause of a number of neurodegenerative diseases and upon which Dr. Steinman relied to support his theory. Tr. 323. Chi hypothesized that interfering with the pathway of ADP-ribosylase could minimize neuronal damage in seizure disorders. Tr. 323; Pet. Ex. 34.[46] Wang tried to inhibit one of the enzymes in the pathway, showing it to be protective in an epileptic rat model. Tr. 323; Pet. Ex. 52.[47] Ying looked at cell cultures of mouse neurons and brain tissue and found that, when ADP-ribosylase activity was inhibited, there was less mortality of cells. Tr. 323-24; Pet. Ex. 53.[48] Dr. McGeady stated that the articles show some support for the idea that ADP-ribosylase is toxic to neurons. Tr. 324. However, "some animal models do apply to humans and some do not. I don't know that I could say these do or do not." Tr. 324. More importantly, the acellular pertussis toxoid used in this case was not at issue in these articles. Tr. 324. The articles only provide an explanation of how the acellular pertussis toxoid could cause neuronal death "if you accept that it has ADP-ribosylase activity. And I don't know that that's been demonstrated." Tr. 324-25. According to Dr. McGeady, he is unaware of the DTaP vaccine causing brain injury or seizures, and the IOM has not accepted such an association. Tr. 333-34.

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[45] W.J. Black et al., *ADP-Ribosyltransferase Activity of Pertussis Toxin and Immunomodulation by Bordetella pertussis*, 240 SCIENCE 656-59 (1988), filed as "Pet. Ex. 33."

[46] Ling-yi Chi et al., *Poly (ADP-ribose) Signal in Seizures-Induced Neuron Death*, 71 MED. HYPOTHESES 283-85 (2008), filed as "Pet. Ex. 34."

[47] Sheng-jun Wang et al., *Poly (ADP-ribose) Polymerase Inhibitor is Neuroprotective in Epileptic Rat via Apoptosis-Inducing Factor and Akt Signaling*, 18 NEUROREPORT 1285-89 (2007), filed as "Pet. Ex. 52."

[48] Weihai Ying et al., *Poly (ADP-ribose) Glycohydrolase Mediates Oxidative and Excitotoxic Neuronal Death*, 98 PROC. NATL. ACAD. SCI. U.S.A. 12227-32 (2001), filed as "Pet. Ex. 53."

Dr. McGeady stated that the Vaccine Injury Table recognizes encephalopathy and encephalitis as possible injuries associated with the whole cell pertussis vaccine, but not the acellular pertussis vaccine. Tr. 334-35. However, he added, "In medicine, you never say never. And I just don't think there's evidence that this does happen." Tr. 336. Moreover, he did not think it happened here. Tr. 335.

Regarding the second part of Dr. Steinman's theory involving alum, Dr. McGeady commended Dr. Steinman on his explanation of "how the nervous system is attacked by the immune system including how exposure to vaccines including influenza vaccine and pertussis vaccine might rarely induce brain disease." Resp. Ex. C at 8. He agreed that Dr. Steinman's mechanism of alum-activated inflammasome neurotoxicity "is consistent with what is known of this innate immune mechanism," but was doubtful that this mechanism was operative in this case. *Id*.; Tr. 328.

Dr. McGeady stated that inflammasomes are an assembly of proteins within a cell and part of the inflammatory process. Tr. 325. Dr. Steinman opined that adjuvants cause crystals that activate inflammasomes, but Dr. McGeady corrected that statement, explaining that what Dr. Steinman described actually requires two signals. Tr. 325. The first signal can be from a variety of sources, including bacterial or pathogen products, or damage to cells, such as loss of potassium from intracellular compartments; the second signal is the activation of the toll-like receptor on the surface or within a cell. Tr. 325-26. The two signals together generate IL-1β, IL-18, and likely IL-33, proinflammatory cytokines which equip an individual to resist a potentially harmful stimulus. Tr. 326. IL-1β is a critical cytokine involved in the inflammatory process. Tr. 326. It binds to a receptor and activates the lining cells of blood vessels, so it becomes more receptive to inflammatory cells. Tr. 326-27. IL-1β can also cause coagulation – blood clotting – and, if it gets to the brain – fever. Tr. 327. "And it also interacts with T cells in the adaptive immune system and causes them to become activated and skewed in a certain direction." Tr. 327. IL-1β is tightly regulated because it is powerful and capable of great damage, so there is a second type of receptor that acts as a decoy and binds to IL-1β so it "doesn't go any further." Tr. 327.

Dr. McGeady agreed that aluminum additives in the subject DTaP vaccines crystallize with the pathogen to cause a physiological response of IL-1β production. Tr. 327-28. "That's why we're giving the vaccine, to try to immunize the person against the pathogen. The pathogen will provide the other signal for the production of IL-1 beta." Tr. 327-28. Dr. McGeady pointed to Dr. Steinman's own research: "Fever, triggered via the cytokine interleukin 1, IL-1, is the quintessential manifestation of the brain reaction to an immune danger signal." Resp. Ex. C at 8-9, quoting Pet. Ex. 32 at 2. There was no literature filed in this matter that suggests that acellular pertussis toxoid can lead to penetration of the blood brain barrier. Tr. 329-30. Dr. McGeady was uncertain how Dr. Steinman's hypothesis or the literature cited applied to Heavenly. He stated Dr. Steinman relied on literature involving the whole-cell pertussis vaccine, rather than the acellular pertussis toxoid vaccine, as well as studies based on animal testing, which Dr. Steinman admitted do not equate to humans. Tr. 218.

4. Analysis

Petitioners have not shown that the acellular form of pertussis toxoid contained in the DTaP has the same effect as the whole-cell formula – or that it could cause brain anomalies present in this case. In fact, cases addressing the acellular form of pertussis vaccine have found the opposite to be true. *See, e.g., Dean on behalf of I.D. v. Sec'y of Health & Human Servs*., No. 13-808V, 2017 WL 2926605 at *18 (Fed. Cl. Spec. Mstr. June 9, 2017) (finding that the petitioners had not shown that the acellular form of pertussis toxoid contained in the DTaP vaccine would necessarily have the same effect as the whole-cell formulation, or that it would cause the specific injury in this case), citing *Taylor v. Sec'y of Health & Human Servs*., 108 Fed. Cl. 807, 820 (2013) (noting that the modern DTaP vaccine has evolved from attempts to minimize the amount of toxin in the vaccine as compared to past versions); *James ex rel. Chee v. Sec'y of Health & Human Servs*., No. 09-284V, 2010 WL 4205699, at *11 (Fed. Cl. Spec. Mstr. Sept. 30, 2010) (stating that the acellular form of the pertussis vaccine is much less toxic than the whole cell form.); *see also Kottenstette v. Sec'y of Health & Human Servs.*, No. 15-1016V, 2020 WL 4197301, at *8 (Fed. Cl. Spec. Mstr. June 2, 2020) (collecting cases describing "why findings relating to the safety of the DTP vaccine are not applicable to the later DTaP vaccine"), *mot. for rev. denied*, 2020 WL 4592590 (Fed. Cl. July 27, 2020), *appeal docketed*, No. 20-2282 (Fed. Cir. Sept. 17, 2020).

While the acellular pertussis vaccine is far less likely to cause the severe reactions associated with the whole cell pertussis vaccine, special masters have found the acellular pertussis vaccine to be responsible for some serious injuries, including complex seizures. *Suchar v. Sec'y of Health & Human Servs*., No. 07-58V, 2010 WL 1370627 at *36-37 (Fed. Cl. Spec. Mstr. March 15, 2010*); Johnson v Sec'y of Health & Human Servs*., No. 07-138V, 2010 WL 3291932 at *15 (Fed. Cl. Spec. Mstr. July 30, 2010) (finding fewer, but similar reactions to DTaP than DPT vaccines are possible; however, the case involved a whole-cell pertussis vaccine); *Teller v. Sec'y of Health & Human Servs*., No. 06-804V, 2009 WL 255622 at *4 (Fed. Cl. Spec. Mstr. Jan. 13, 2009) (special master noted that an acute neurological injury following DTP vaccination is possible, and thus it is possible following a DTaP vaccine but less likely).

Succinctly, however, prior decisions have addressed the distinction between the DTP and DTaP formulations of vaccines, the former utilizing whole-cell pertussis while the latter uses acellular pertussis toxin. These cases have persuasively explained at length why findings relating to the safety of the DTP vaccine are not applicable to the later DTaP vaccine, which was specifically developed to address safety concerns related to the earlier, whole-cell DTP formulation. *See, e.g. Taylor v. Sec'y of Health & Human Servs.*, No. 05-1133V, 2012 WL 4829293, at *30 (Fed. Cl. Spec. Mstr. Sept. 20, 2012) ("…it is well established that, while pertussis toxin may be capable of causing neurological damage, vaccination, especially modern-day vaccination with the acellular form, is generally safe…"), *aff'd*, 108 Fed. Cl. 807 (2013); *Holmes v. Sec'y of Health & Human Servs.*, No. 08-185V, 2011 WL 2600612, at *20 (Fed. Cl. Spec. Mstr. Apr. 26, 2011) (criticizing petitioner's expert for "extrapolating from studies of the DPT vaccine to the DTaP vaccine"); *Simon v. Sec'y of Health & Human Servs.*, No. 05-941V, 2007 WL 1772062, at *7 (Fed. Cl. Spec. Mstr. June 1, 2007) ("However, the neurological events following the DTaP vaccination are greatly reduced to only around 30-40 percent of the reaction rate seen following the DTP vaccination... Thus, it appears that the DTP Studies cannot be used to support DTaP causation"); *Grace v. Sec'y of Health & Human Servs.*, No. 04-[redacted], 2006 WL

3499511, at *9 (Fed. Cl. Spec. Mstr. Nov. 30, 2006) (finding petitioner's expert unpersuasive due to a failure to explain why evidence concerning possible harmful effects of the DTP vaccine could be automatically extrapolated to apply to the DTaP vaccine). These decisions make clear that epidemiological findings relating to the safety of DTP vaccines cannot reasonably be said to relate to the DTaP vaccine at issue in this case.

Dr. Steinman's theory is premised on the DTaP vaccine triggering an immune reaction that could affect the brain, causing neuronal death, albeit to a lesser extent than the DTP vaccine, though he does not distinguish between the two formulations and relies on literature and testing involving the whole cell pertussis vaccine. I am unpersuaded by this logic. Even if I were to fully accept that the residual pertussis toxin that remains in the DTaP vaccination is capable of such a reaction, the literature submitted specifically addresses the whole-cell pertussis vaccine and, without more, prevents extrapolating alleged vaccine reactions from one formula to the other. The specific history of safety concerns with the DTP vaccine and the subsequent improvement with the DTaP vaccine are discussed in the above-referenced decisions. In other words, without more and on this record, Dr. Steinman's opinion based on whole-cell pertussis vaccine studies does not correlate with the acellular pertussis vaccine and he has provided nothing more than speculation. Dr. Steinman himself has "conceded that much of the literature offered in support" of his ADP-ribosylation theory is "outdated." *See Zumwalt on behalf of L.Z. v. Sec'y of Health & Human Servs*., No. 16-994V, 2019 WL 1953739, at *17 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (rejecting Dr. Steinman's theory that excessive ADP ribosylation can play a neuropathic role leading to seizures and neuronal death), *mot. for rev. denied*, 146 Fed. Cl. 525 (2019); *see also Downing-Powers v. Sec'y of Health & Human Servs*., No. 15-1043V, 2020 WL 4197303, at *16 (Fed. Cl. Spec. Mstr. June 2, 2020) (describing Dr. Steinman's ADP ribosylation theory as "extremely vague and unpersuasive").

Medical literature is not required for a theory to be found "sound and reliable." *Andreu*, 569 F.3d at 1379. However, Dr. Steinman has offered a theory with no "indicia of reliability" to support it. *Moberly*, F.3d at 1324. The issue in this case is whether congenital brain anomalies can be caused or aggravated by the acellular pertussis toxin. Dr. Steinman has offered no explanation or evidence to support petitioners' contention that the acellular pertussis toxin can either cause or significantly aggravate the structural brain defects that are present in this case.

Petitioners have failed to proffer a sound and reliable medical theory, and as such, cannot satisfy *Althen* Prong 1 or *Loving* Factor 4.

B. *Althen* Prong 2/*Loving* Factor 5: Logical Sequence of Cause and Effect

1. Dr. Mauney's Opinion

Petitioners initially relied on Dr. Mauney, Heavenly's treating neurologist. In his report, Dr. Mauney wrote that Heavenly's June 8, June 28, and August 2, 2010 examinations were normal. Pet. Ex. 23 at 1. However, he asserts that after receipt of the first DTaP vaccination on August 2, 2010, she was seen for a "sick visit" on August 16, 2010, at which time her caregivers complained that she slept all day. *Id*. at 2. At another "sick visit" on September 24, 2010, the pediatrician could not get Heavenly to focus on faces. *Id*. "[M]ultiple developmental problems" were noted at a visit

on September 28, 2010, when Heavenly was administered the second DTaP vaccination. *Id*.

Relying on a history provided by Ms. Martin, Dr. Mauney wrote that Heavenly's development was normal prior to receiving her two-month-old DTaP vaccination, but afterwards, she "slept significantly longer" and, when she was awake, "she was not alert and did not interact as she had before." Pet. Ex. 23 at 2. "These changes resulted in developmental concerns recorded by her pediatricians." *Id*. Dr. Mauney noted that between her two- and four-month vaccinations, Heavenly's head circumference dropped from the 25th percentile to the 3rd percentile. *Id*. Ms. Martin also reported that after the second DTaP vaccination, Heavenly was screaming, would not respond appropriately, and had difficulty feeding and holding her arms up. *Id*.

Dr. Mauney opined, "It is well know[n] and accepted in the medical community that in rare cases, [the DTaP] vaccine can cause injury to the central nervous system." Pet. Ex. 23 at 3. In his opinion, Heavenly "suffered a severe encephalopathic injury" caused by the DTaP vaccine. *Id*. The "significant change" in her sleep pattern "is a known symptom of encephalopathy." *Id*. Further, the decrease in head circumference from the 25th percentile to the 3rd percentile in a span of two months indicated that "Heavenly's brain stopped growing at two months of age." *Id*.

According to Dr. Mauney, it was "very unlikely that she was born with this brain condition" because it "failed to manifest until she was two months old" and "[i]f she had been born with this condition she would not have had normal exams up to two months of age." Pet. Ex. 23 at 3. Testing for underlying genetic causes was normal and "[o]ther causes for her encephalopathy have failed to manifest," the DTaP vaccine, "a known encephalopathic agent," was the cause of Heavenly's condition. *Id*.

Based on the facts provided by Ms. Martin, Dr. Mauney further opined that Heavenly "responded adversely to her four month Dtap vaccination and [had] a significant regression in development at that time…this second vaccination should not have been administered" and "may show a hyper-sensitivity to this vaccine." Pet. Ex. 23 at 3. He cited to the records of Heavenly's four-month well-child visit on September 28, 2010 that noted concern for failure to meet some development milestones, with the next record entry on October 1, 2010 showing "grave concerns and significant developmental regression." *Id*. Dr. Mauney documented the October 1, 2010 as Ms. Martin "complains that Heavenly has stopped interacting with people." *Id*. at 2.

In Dr. Mauney's opinion, Heavenly suffered significant neurologic regression at two months of age after receiving her first DTaP vaccination, which may have worsened after her second DTaP vaccination. Pet. Ex. 23 at 2. Based on his "understanding… Heavenly's adverse reactions to these vaccinations started in very close temporal relationship to these vaccines… this is an appropriate time frame for the Dtap vaccine to cause an adverse reaction." *Id*. at 4.

While Dr. Mauney documented his receipt of "…a set of Heavenly's medical records" he did not document her neurological history in his report. Pet. Ex. 23 at 1-2. He did not discuss Heavenly's MRI of November 10, 2010 or EEGs performed on November 11, 12 and 15, 2010. *See* Pet. Ex. 4 at 118; Pet. Ex. 8 at 57, 61-62, 102, 107; Pet. Ex. 9 at 48. Dr. Mauney further failed to address any of the congenital brain anomalies present on the November 10, 2010 MRI which included Dandy-Walker variant, cerebral dysgenesis, diffuse cortical atrophy, and thinning of the

corpus callosum. He also did not address early records documenting Heavenly's failure to thrive and the reduction of her head circumference between birth and the August 2, 2010 visit prior to her first DTaP vaccination focusing instead on the records between August 2, 2010 and October 1, 2010 and the history provided by Heavenly's caretakers over a year after the events.

2. Dr. Steinman's Opinion

Dr. Steinman initially opined that Heavenly's two- and four-month old DTaP vaccinations "caused a precipitous decline in her neurologic function." Tr. 146; Pet. Ex. 29 at 1. He added that "if" Heavenly had preexisting Dandy-Walker variant, her "clinical course was consistent with a significant aggravation…of neurologic development" following the two-month and four-month DTaP vaccinations. Pet. Ex. 29 at 1.

According to Dr. Steinman, development in infants occurs at the two- and four-month marks, when they start doing things like sitting up, crawling, walking, and talking, which in this case "hadn't yet happened." Tr. 176-77. "[M]y judgment is that the vaccines aggravated her condition…. She was shoved into this [w]retched condition that she may not have been in, if not for the vaccine." Tr. 177. "[I]f not for what happened during those vaccinations at month two and month four, she wouldn't be the way she is. And I base that on as much objective evidence as I could find in the record, which isn't a lot." Tr. 176.

Dr. Steinman agreed Heavenly was born with "a variant of Dandy-Walker syndrome," which he described as a collection of findings, most notably cerebellar atrophy in the midline, where hydrocephalus occurs in some cases and poor brain development in others, and "the brain is microcephalic and small." Tr. 174. He added it is a form of cerebral dysgenesis, which means the brain did not develop correctly, but added "cerebral dysgenesis" alone does not indicate the severity of the condition. Tr. 178-79; Pet. Ex. 29 at 1. He described cortical atrophy as the cerebral cortex not developing to the fullest, which can also occur but may not result in significant abnormalities. Tr. 179. "The main brunt" of Dandy-Walker is borne by the posterior brain, specifically the midline structure of the cerebellum. Tr. 179.

Dr. Steinman described the corpus callosum as a band of fibers that connects the two hemispheres of the brain. Tr. 174-75. When there is damage to either hemisphere, it will cause thinning of the corpus callosum, sometimes referred to as an "accompaniment" to Dandy-Walker. Tr. 174-75, 180. "Having abnormalities of the corpus callosum is usually a – a bad sign." Tr. 180. However, "there's a wide, wide range of outcome[s] when somebody carries the diagnosis of Dandy-Walker, ranging from people who are normal to people who are at the other extreme, like Heavenly." Tr. 175; Pet. Ex. 29 at 1.

Dr. Steinman agreed that Heavenly was born with Dandy-Walker syndrome and associated congenital abnormalities. Tr. 176. He agreed the DTaP vaccine was not the cause of these brain abnormalities. He provided a detailed description of these congenital abnormalities and the devastation they cause but maintained at hearing that the DTaP vaccines Heavenly received were responsible for the condition she was in, rather than Dandy Walker and other abnormalities. Tr. 174. He stated all the prenatal testing was normal, with no abnormalities noted on any of the sonograms, including the third trimester sonogram, which looks at the brain. Tr. 147-50; Pet. Ex.

21 at 12-16, 23. "Certain abnormalities should have been visible if they were significantly abnormal. Very subtle things sometimes are not picked up. But [it] has all the appearances of being a normal study." Tr. 148-49. Ultimately, Dr. Steinman agreed that brain abnormalities can be missed on sonograms, and that MRIs are far superior to sonograms in assessing brain structures. Tr. 194.

Dr. Steinman further stated the only abnormality Heavenly had at birth was "some jaundice." Tr. 151. Her APGARs were nine and nine. Tr. 151; Pet. Ex. 2 at 6. At her pediatric visits on June 8, 2010 and June 28, 2010, her height, weight, temperature and muscle tone were deemed normal. Tr. 153-55; Pet. Ex. 29 at 4, citing Pet. Ex. 3 at 23-24. Dr. Steinman agreed that the records reflect a drop in Heavenly's head circumference from the 50th percentile at birth to the 25th percentile on June 28, 2010 but reasoned, "If the measurements were absolutely reliable, it would be of concern. But since usually you do it with a paper tape, it – it's a very low tech measurement." Tr. 156. Head circumference could "have a certain amount of variability." Tr. 194; Pet. Ex. 2 at 49. Dr. Steinman agreed that there was no indication that a neurological examination was performed or that developmental milestones were documented during the June visits. Tr. 197.

Dr. Steinman opined that, at two months of age on August 2, 2010, Heavenly was normal; her head had grown from 35.5 cm to 37.75 cm but remained in the 25th percentile, which he deemed normal. Tr. 156-57. Her height and weight were in the 5th and 3rd percentiles, so formula was recommended to help her gain weight. Tr. 157. Pentacel, Prevnar, and rotavirus vaccinations were administered at this appointment. Tr. 156.

According to Dr. Steinman, within 72 hours of the first DTaP vaccine on August 2, 2010, "there was a change in the trajectory of Heavenly's neurologic development;" therefore, she should not have been given the four-month vaccinations, which significantly aggravated her condition. Pet. Ex. 29 at 9. He submitted that CDC literature states, "Contraindications to further vaccination with DTaP are a severe allergic reaction (anaphylaxis) to a vaccine component or following prior dose of vaccine, and encephalopathy not due to another identifiable cause occurring within 7 days of vaccination." Pet. Ex. 31 at 14. "Certain infrequent adverse reactions following DTaP vaccination are considered to be precautions for subsequent doses," and include "a temperature of 105°F (40.5°C) or higher within 48 hours that is not due to another identifiable cause; collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours; persistent, inconsolable crying lasting 3 hours or longer, occurring within 48 hours; and convulsions with or without fever occurring within 3 days." Pet. Ex. 29 at 9, quoting Pet. Ex. 31 at 14. Dr. Steinman conceded that Heavenly showed no such reaction after her vaccines. Tr. 215-16.

Dr. Steinman interpreted the August 16, 2010 as a "sick visit," because "it was reported that she sleeps all day" and even though she was noted as "alert," this "may certainly be a manifestation of encephalopathy." Pet. Ex. 29 at 4; Pet. Ex. 3 at 22. Dr. Steinman acknowledged this visit was two weeks after her vaccinations and was a scheduled visit for weight check. Tr. 158. He acknowledged the record reflected "alert," "comfortable," "[a]nemia consistent with malnourished," and that further workup and hospitalization would be necessary if her activity decreased. Tr. 158. He claimed that a conflict existed between "alert" and "sleeps all day," then stated based on the caretakers' testimony earlier that day, in his opinion, the change in Heavenly's sleep pattern was "of high level of significance." Tr. 158-59. However, when confronted with Ms.

O'Quin's testimony that Heavenly slept all day but was awake all night and active when awake, he agreed that it was not unusual for a two-month-old to be backward in sleep patterns. Tr. 159-60.

Dr. Steinman agreed that encephalopathy includes sleepiness, lethargy, inability to arouse, irritability, and crying, and that Ms. O'Quin testified that, when awake, Heavenly was alert and active in the weeks following her two-month vaccinations. Tr. 161. However, he maintained that "a change in the sleep pattern" was significant. Tr. 161. He then pivoted, stating, "But one of the encephalopathic complications of the pertussis vaccine [came] up after the next vaccination…this is a real life problem…so, I don't put a huge amount of weight on any one point." Tr. 161-62.

Dr. Steinman added that the pediatric record for September 10, 2010, which documented no other complaint other than Heavenly being "gassy," did not rule out her sleeping as still an issue. Pet. Ex. 29 at 4.

Dr. Steinman stated that the September 24, 2010 visit, at which the pediatrician documented "unable to get Heavenly to focus on face," was the first notation of a tracking or visual issue, which could indicate a pathobiological problem, a brain problem, or both. Tr. 163-64; Pet. Ex. 3 at 2. He agreed that this visit was four days prior to her receipt of the second set of vaccinations. Tr. 201-02.

Dr. Steinman agreed that the September 28, 2010 visit noted Heavenly as small and developmentally behind, with questionable vison. Pet. Ex. 29 at 5, citing Pet. Ex. 3 at 18. Her height and weight were in the 10th percentile and her head circumference was in the 3rd percentile. *Id*. He read the record as Heavenly having met the developmental milestones of smiling, recognizing her parents' voices, and opening her hands, but was unable to laugh, raise her trunk to prone, roll over, or reach for or slap objects with her hands. *Id*. According to Dr. Steinman, she was then given immunizations and lost many of these milestones. *Id*.; Tr. 164-65.

When questioned about the milestones he claimed that Heavenly lost, Dr. Steinman stated that his report was written in 2016, without the benefit of the caretakers' testimony, and was based on Ms. Martin's phone calls to the pediatrician documented on October 1 and October 18, 2010. Tr. 203-04; Pet. Ex. 29 at 5. Dr. Steinman stated that in her October 1, 2010 phone call, Ms. Martin reported that Heavenly was not reaching for things and did not seem to recognize people, and "today," Ms. Martin testified to inconsolable crying following the September 28, 2010 vaccinations, which are "pretty characteristic of a reaction to pertussis vaccine…. It's a manifestation of an encephalopathy, yes." Tr. 170; Pet. Ex. 29 at 5, citing Pet. Ex. 3 at 17. When shown the medical record for October 1, 2010, which did not document any complaint of inconsolable crying in the 72 hours following the September 28 vaccinations or other definable reaction, Dr. Steinman stated that Heavenly not reaching for things may be "because of general hypotonia, that she can't position herself to do that." Tr. 170-71. Dr. Steinman ultimately conceded there was no evidence Heavenly suffered fever, shock-like collapse, inconsolable crying or convulsions within 72 hours of either her August 2, 2010 or September 28, 2010 vaccinations. Tr. 215-16.

Dr. Steinman agreed that a two-month-old infant would not reach for objects, hold bottles,

or pull up from their backs. Tr. 194-95. He agreed that most of the developmental milestones expected at four months were not met. Tr. 198. But he added that the lack of "obligate fisting" was a "manifestation of motor damage." Tr. 198. He then stated that the line drawn diagonally through the list of milestones in the record was unclear as to whether that meant all milestones were present or all were negative. Tr. 200. He noted that the record documented her motor tone as normal but disagreed with the accuracy of the record. Tr. 198-99; Pet. Ex. 3 at 18.

Dr. Steinman acknowledged the drop in Heavenly's head circumference from the 25th percentile to the 3rd percentile between June 28 and September 28, 2010, was "a significant fall," "of concern," and "worrisome," but argued that between June 28 and August 2, 2010, she remained in the 25th percentile, which was normal. Tr. 165-67. "[W]e're looking at head circumference and using it generally as a surrogate for brain growth. But it's just the size of the skull," which expands to accommodate brain growth. Tr. 168. Dr. Steinman stated that, between August 2nd and September 28th, Heavenly's head circumference fell from the 25th percentile to the 3rd percentile, with visual problems and sleep issues, which could be neurological issues. Tr. 168-69. Dr. Steinman did not address the decline in head circumference from the 50th percentile at birth to the 25th percentile at one month of age. *See* Pet. Ex. 3 at 24; Tr. 188-90.

Dr. Steinman discussed the November 9, 2010 visit to the geneticist, at which Heavenly was described as hypotonic and microcephalic. She did not follow, and the fontanel had closed. Tr. 172-73; Pet. Ex. 7 at 1. She also had abnormal posture with extension response and lethargic appearance but did not have any recognizable dysmorphic features. Tr. 173. In Dr. Steinman's opinion, a closed fontanel and a small head are "highly indicative of something [that] happened to the brain." Tr. 173. In his opinion, the hypotonia and microcephaly were the result of the August 2nd and September 28th vaccines. Pet. Ex. 29 at 5.

Dr. Steinman discussed the MRI in November 2010 as showing "vast amounts" of neuronal death, as well as the absence of connections of the brain that should have been there, stating, "[S]omewhere in the developmental program or somewhere from an environmental insult, there's been a lot of death in her brain…it's incontrovertible in my opinion." Tr. 218. He disagreed that Heavenly's brain never developed in utero; but rather, opined that the absent parts of the brain were the result of a "death event" disrupting the program that led "to these big holes in the brain" seen on the MRI. Tr. 218-19. "I'm basing my theory on aggravation…so I'm talking that some of the holes that we see on the imaging are due to that environmental insult, in this case the vaccine, in an unfortunately susceptible kid." Tr. 219.

In his report, Dr. Steinman opined that the November 2010 MRI showed brain injury "diffusely all over." Pet. Ex. 68 at 4. "Most notably, her brain stopped growing at two months, when she received the first set of vaccines, therefore, the MRI shows large areas of CSF that should have brain matter in them and instead only have cerebrospinal fluid." *Id*. at 5. He opined that her head was growing normally prior to her nine-week-old vaccinations but stopped growing after. *Id*. Dr. Steinman also asserted that the cortical atrophy seen on the MRI was the result of the pertussis toxin which caused necrosis of the neurons and caused Heavenly's brain to stop growing after her DTaP vaccinations. *Id*. Again, Dr. Steinman disregarded the drop in Heavenly's head circumference from the 50th at birth to the 25th percentile within the month following her birth.

At hearing, Dr. Steinman agreed that Heavenly's MRI showed Dandy-Walker syndrome, vermian hypoplasia, and supratentorial abnormalities, and that all are congenital abnormalities present at birth. Dr. Steinman agreed that none of these abnormalities were caused by the pertussis vaccine. He maintained, however that the pertussis vaccine aggravated those congenital abnormalities. Tr. 208-210. "[T]here was something akin to a severe downhill course after the first and second vaccinations. And I'm basing it on the change in head circumference, loss of milestones, and the visual abnormality." Tr. 210; Pet. Ex. 68 at 4. Dr. Steinman added that one could say "that all of these things would have happened with or without the vaccine…but I don't say it because I don't think it's the case." Tr. 210. Dr. Steinman ultimately agreed that Heavenly did not lose milestones, but rather never attained them. Tr. 210-11.

Dr. Steinman was questioned about the content of Resp. Ex. S,[49] which noted that fetuses with isolated posterior fossa abnormalities can have normal developmental outcomes but those with additional intercranial anomalies, like Heavenly, had worse outcomes. Dr. Steinman deflected, stating that the article discussed findings on prenatal MRIs, and Heavenly did not have a prenatal MRI. Tr. 212-13. "You can call it Dandy-Walker plus or whatever you want. She has severe damage. There's no doubt. A lot of it is congenital…I am arguing that there's an aggravation here. And I don't know how much of the damage that we see is due to the aggravating circumstance." At this juncture, it appeared that Dr. Steinman abandoned his opinions that pertussis vaccine "caused" the damage seen pivoting to only significant aggravation of the already present at birth damage to the brain. Tr. 213.

Dr. Steinman disagreed with Dr. Holmes's opinion that pertussis encephalopathy leaves a "mark" or "portrait of such a condition" on the brain that can be seen on an MRI. Pet. Ex. 68 at 2. However, petitioners' submitted literature seems to differ. *See, e.g.*, Pet. Ex. 73 at 1 (Case report noting that a child who developed recurrent seizures and acute encephalopathy after receiving a whole-pertussis vaccination had a normal MRI). However, Hiraiwa-Sofue,[50] a case report on a child who developed encephalitis/encephalopathy after suffering from a pertussis infection, noted that the MRI "indicated that marked demyelination without cytotoxic edema may have occurred to the patient…this is the first report to show precise MRI findings of pertussis-associated encephalitis/encephalopathy. Markedly increased myelin basic protein levels in the cerebrospinal fluid were consistent with the MRI findings." Pet. Ex. 72 at 1. Another case report, Aydin,[51] discussed a child who developed lethargy, hypotonia, and focal clonic seizures six days after receiving a whole-cell pertussis vaccination and was diagnosed with acute necrotizing encephalopathy ("ANE"). Pet. Ex. 74 at 1. Dr. Steinman noted that the patient's MRIs showed a "different 'mark'" than the patient in Hiraiwa-Sofue. Pet. Ex. 68 at 4. Aydin noted that whole-cell pertussis vaccination "has not been previously reported in association with ANE" and found that "[t]he presence of haemorrhage, localized atrophy or cystic encephalomalacia in the brain lesions

[49] *See supra* n.16.

[50] Ayako Hiraiwa-Sofue et al., *Pertussis-associated Encephalitis/Encephalopathy with Marked Demyelination in an Unimmunized Child*, 320 J. NEUROL. SCI. 145-48 (2012), filed as "Pet. Ex. 72."

[51] Hale Aydin et al., *Acute Necrotizing Encephalopathy Secondary to Diphtheria, Tetanus Toxoid and Whole-Cell Pertussis Vaccination: Diffusion-Weighted Imaging and Proton MR Spectroscopy Findings*, 40 PEDIATR. RADIOL. 1281-84 (2010), filed as "Pet. Ex. 74."

was reported as a significant prognostic imaging finding." Pet. Ex. 74 at 2-3. Dr. Steinman concluded that, due to his vast experience with pertussis vaccine, he knows of no "'portrait on MRI' that should be seen, or not seen, to rule out the vaccine as the cause of Heavenly Martin's injury," as asserted by Dr. Holmes. Pet. Ex. 68 at 4. According to Dr. Steinman, these articles show demyelination of the brain as a result of infections, drugs, and toxins following exposure to *B. pertussis* virus or whole-cell pertussis vaccine.

There is no apparent argument amongst the experts that encephalitis/encephalopathy caused by infections, toxins, and drugs can cause demyelination, however, Dr. Steinman presented nothing to explain the finding of delayed myelination on Heavenly's MRI, or the brain's failure to produce myelination in this first place.

Dr. Steinman conceded that the November 2010 MRI showed Dandy-Walker variant, microcephaly, cortical atrophy, and thinning of the corpus callosum, "which encompasses a wide spectrum of neurologic outcomes ranging from severe retardation to normal development." Tr. 204-05. However, he maintained, "Knowing that she had a Dandy-Walker and knowing what pertussis can do…one asks oneself, well, why did the medical system, the neurologist and the geneticist do a full court press looking for everything else." Tr. 206. In Dr. Steinman's opinion, Heavenly's treating physicians were not content to simply attribute her condition to Dandy-Walker variant and they continued running tests. Tr. 206. This carried a lot of weight for him. Tr. 207. Further, Dr. Mauney wrote a report concluding that the vaccines were responsible for Heavenly's condition. That was influential as well. Tr. 206-07. Dr. Steinman admitted that the doctors would have been remiss if they did not run the testing that they did.

Further, Dr. Steinman stated any problems caused by Dandy-Walker variant would have been apparent at birth or during the first two months of life. Tr. 190-91. If Heavenly's condition was caused by Dandy-Walker variant alone, she would have been "devastated all along" and failed to meet milestones. Tr. 191. Dr. Steinman conceded that failure to thrive is a characteristic of Dandy-Walker variant but attributed Heavenly's failure to thrive to feeding problems. Tr. 191-92; Pet. Ex. 58 at 2. He later contradicted this statement, opining that, though she had failure to thrive in the first two months of life, her feeding activities were "good enough to sustain her," and she gained weight after her formula was changed. Tr. 195. Though not a milestone, Dr. Steinman testified that the absence of being able to feed correctly is evidence of brain damage. Tr. 195.

3. Dr. Holmes's Opinion

Like Dr. Steinman, Dr. Holmes analyzed Heavenly's medical records, noting that she "appeared to be normal" at birth; her weight and height were at the 50th percentile, and her head circumference was either at the 50th or 75th percentile but both would be normal. Tr. 236-38; Pet. Ex. 2 at 49; Resp. Ex. A at 1-2.

However, Dr. Holmes noted that, at the June 8, 2010 visit and June 28, 2010 visit at one month of age, her height and weight were in the 10th and 10 to 25th percentile respectively; her head circumference had dropped to the 25th percentile. Tr. 239-40, 299; Resp. Ex. A at 2; Pet. Ex. 3 at 24-25. To Dr. Holmes, the decline in head circumference since birth was concerning. Tr. 240. He added the record on "development" was unclear but explained that "motor and tone" is a

neurological, not a developmental assessment, and in babies, muscle tone abnormalities can be either increased tone (hypertonia) or decreased tone (hypotonia). Tr. 240-41. Dr. Holmes was unclear whether a motor and tone exam was conducted. Tr. 240.

At the August 2, 2010 two-month well visit, Heavenly's weight was in the 3rd percentile, her height was in the 5th percentile, and her head circumference maintained at the 25th percentile. Tr. 241-42; Pet. Ex. 3 at 23. She was not growing well, and her head circumference had declined prior to the first set of vaccinations. Tr. 242-43. When asked about Ms. Martin's testimony that Heavenly was "pulling up," reaching for toys and objects, and following her finger when she read to her, Dr. Holmes responded that none of those actions are typical milestones for a two-month-old child. Tr. 244. Rather, "[h]ealthy two-month-old children would…move the lower extremities. They may turn to their mother's voice. They may turn to a sound. And they may go from a – sort of a reflexive smile that's a reflex at birth to one where they begin to smile spontaneously at two months." Tr. 243. Dr. Holmes added, "There's not a whole lot they do developmental[ly], which is why a lot of pediatricians do not even do developmental assessments early on until they get to be about four months of age." Tr. 244. In his opinion, the only signs of delay at this visit were Heavenly's growth measurements. Tr. 244-45.

The August 16, 2010 visit reflected that Heavenly was "gassy," could go for days without stools, and slept all day. Tr. 245-46; Pet. Ex. 3 at 22. Dr. Holmes attributed no significance to Heavenly sleeping all day. "Infants sleep a lot…at this age, she should be sleeping about 16 hours a day." Tr. 246. He pointed to the pediatrician's action as important; the pediatrician woke Heavenly, noting her to be alert when aroused. Tr. 246. Weight gain was poor and blood work was ordered, which showed anemia and malnutrition. Tr. 247. The plan was to wait one more week and if Heavenly was not gaining weight, she would be hospitalized. Tr. 247. Dr. Holmes pointed to no evidence in the medical record that Heavenly suffered fever, shock collapse, inconsolable crying or convulsions between her vaccinations on August 2 and her August 16, 2010 visit. Tr. 247-48. "No acute changes in neurological function or behavior were reported after the first set of vaccinations." Resp. Ex. A at 11.

Dr. Holmes noted the August 27, 2010 visit as a weight check. Heavenly weighed nine pounds, six ounces; she was in the 5th percentile for weight. Tr. 248-49; Pet. Ex. 3 at 21. She was given a hepatitis B vaccine. *Id*. At another weight check on September 9, 2010, Heavenly was ten pounds, three ounces, and "very gassy." Tr. 249-50; Pet. Ex. 3 at 21. Her weight was now near the 5th percentile, which was "very low" and "malnourished." Tr. 249-50.

Dr. Holmes noted on September 20, 2010, Heavenly was sleepy but could be aroused. She had a rash. The grandfather had shingles. Tr. 250; Pet. Ex. 3 at 20. Dr. Holmes was not concerned about Heavenly being sleepy. Tr. 250. A phone call from Ms. Martin to the pediatrician on September 23 reported that Heavenly was having pain with urination but no other concerns were raised about Heavenly's development. Tr. 251.

At her September 24, 2010, Heavenly had "scattered bumps on her chest, abdomen, and buttocks" thought to be a viral rash. Tr. 251; Pet. Ex. 3 at 19. The pediatrician wrote, "[u]nable to get Heavenly to focus on face. Grandmother says she does focus at home. Watches TV." Pet. Ex. 3 at 19. According to Dr. Holmes, this was "medically significant" because "[a] four-month-old

should be following quite well at that point" and focusing on the face. Tr. 252. He added that, by four months old, a child should be smiling, interacting, moving all four extremities, batting objects, and bringing her hands to her mouth. Tr. 252-53. When laying on her belly, she should be able to life up her head, and she should be beginning to roll from front to back. Tr. 253. Of note, Dr. Holmes testified that the caregivers raised no concerns at this visit of any symptoms that could be associated with an encephalopathy following the first set of immunization or any developmental regression after the first immunizations. Resp. Ex. A at 11.

Dr. Holmes noted Heavenly's failure to meet her milestones at her four month visit on September 28, 2010 visit. Tr. 254; Pet. Ex. 3 at 18. She was in the 10th to 25th percentile in height, 10th percentile in weight, and 3rd percentile in head circumference. Tr. 254. The change in head circumference from the 25th percentile to the 3rd percentile indicated that Heavenly's brain was not growing well compared to a normal baby, and she was "falling off the curve." Tr. 254-55. The pediatrician was concerned and referred the family to the ophthalmologist. Tr. 255. The record documents "small, developmentally behind, questioned vision." Tr. 255; Resp. Ex. A at 11. She was given the second set of vaccinations. Resp. Ex. A at 11. "As with the first immunizations, no acute changes were noted after this set of immunizations." *Id*.

Dr. Holmes noted Ms. Martin's phone call on October 1, 2010 to the pediatrician, in which she expressed concerns that Heavenly was not reaching for objects and did not seem to recognize people, as the very same concerns the pediatrician voiced to Heavenly's caretakers at the September 28 visit, prior to the second set of vaccinations. Resp. Ex. A at 12. Ms. Martin raised no other concerns or new deficits in the October 1st phone call. *Id*.

In discussing Dr. Mauney's opinions, Dr. Holmes pointed out that Dr. Mauney's initial impression in October of 2011 was a metabolic disorder with "no clear cause for her encephalopathy." Resp. Ex. A at 12, citing Pet. Ex. 10 at 10. Dr. Holmes further noted that Dr. Mauney's records did not document any neurological deficits related to vaccines., but years later, his report stated her condition was the result of immunizations. *Id*.

Dr. Holmes provided a detailed analysis of Dandy-Walker malformations and the findings on Heavenly's MRI in support of his opinion that Heavenly's developmental delay was the result of severe cerebral malformation, Dandy-Walker variant, and more. Tr. 255-56, 292-93. He explained, "Dandy-Walker malformations are defined by the classic triad of complete or partial agenesis of the cerebellar vermis; cystic dilation of the 4th ventricle; and enlarged posterior fossa with the upward displacement of the tentorium, torcula and transverse sinuses." Resp. Ex. M at 1. The posterior fossa is the back of the brain, the lowest part of the brain next to the brain stem, right above the spinal cord. Tr. 264. The right lower quadrant is the vermis; the cerebellum connects to the brain stem. Tr. 264. Dandy-Walker variant develops in utero within the first trimester of pregnancy and is an abnormality in the cerebellum in which the vermis is malformed; it can lead to a cyst, a fluid-filled cavity in and around the cerebellum, which connects with the forward ventricle. Tr. 256; Resp. Ex. M at 1 ("The formation of the cerebellar vermis begins in the ninth week of gestation…until the total formation of the vermis is completed at the end of the fifteenth week. Thus, this is a condition that occurs early in gestation"). The cerebellum is misplaced upward. Tr. 256; Resp. Ex. M at 1. Though Dandy-Walker variant can be picked up on sonogram, it is sometimes missed. Tr. 256-57. "[T]his was a problem that was there at the time of birth." Tr.

257. It is not uncommon that Dandy-Walker is missed on sonogram, as "it's hard for them to see a cerebral maldevelopment unless it's very obvious." Tr. 293. Sonograms are good at picking up on hydrocephalus and head circumference, but Heavenly was normal at birth. MRIs are far superior to ultrasounds, "[s]o we're often imaging children based on ultrasound findings that are very equivocal." Tr. 293. He added that a good sonogram "may have been able to pick that up." Tr. 293.

Dr. Holmes then compared images of Heavenly's November 2010 MRI to images of a normal brain in order to demonstrate the findings of Dandy-Walker variant, diffuse cortical atrophy, and a thin corpus callosum. Tr. 258, 260; Pet. Ex. 9 at 27; Resp. Ex. X at 1.[52] He explained that the cerebral dysgenesis seen on the MRI was the cause of her microcephaly, hypotonia, and seizures. Resp. Ex. A at 12. There was "cystic enlargement of the posterior fossa which communicates the fourth ventricle. There is vermian hypoplasia. There is diffuse cortical atrophy…The corpus callosum is thinned." *Id.* at 14. Dr. Holmes added that Heavenly's cerebral cortex was not growing, which is why she was "devastated." Tr. 292. These are not abnormalities that can be caused by immunizations, they "are indicative of an in-utero process that preceded the immunizations." Resp. Ex. A at 14-15.

Dr. Holmes detailed what was shown on the MRI sequences. Looking at the middle of Heavenly's head for inflammation, edema, and cell injury, "no acute diffusion abnormalities are noted." Tr. 263. The sagittal view, which is the front to back of the head, shows the cerebral cortex at the top of the brain from the forehead to the back of the head; it includes the frontal lobe and central and occipital regions. Tr. 263-65; Resp. Ex. X at 2. The temporal lobe is from the ear region to the top of the head. Tr. 265-66. This view of Heavenly's brain showed "a big gap full of spinal fluid" between Heavenly's brain and her skull. This is diffuse cortical atrophy, or maldevelopment of the brain. Tr. 266-67. "There should be brain there, but there's fluid there." Tr. 267. The image from behind the head forward to the nose shows a "tremendous amount of atrophy between the brain and skull." Tr. 280; Resp. Ex. X at 5. Dr. Holmes stated the MRI of Heavenly's brain "looks pretty normal as far as how it's developed. But it just hasn't developed. So these [white areas on the MRI] should go all the way out to the cortex, all the way out to the skull." Tr. 282-83; Resp. Ex. X at 9. Dr. Holmes compared Heavenly's MRI to the MRI of a normal five-month-old, pointing out that Heavenly's brain had fluid where a normal brain had white matter. Tr. 284 ("Again, with all of this white being fluid versus what the normal brain should look like").

Dr. Holmes testified that he is not a board-certified radiologist or neuroradiologist, but he reads MRIs in his daily practice and works with a radiologist with whom he reads film sequences. Tr. 306-07. He added, unlike the radiologist or neuroradiologist, he has the benefit of the child's history when he reads films, so he may read the films differently. Tr. 307-08.

Dr. Holmes then discussed the malformation of the vermis as another predictor of Heavenly's poor neurological outcome. Tr. 277. The vermis is located in the middle of the

[52] Petitioner's counsel raised an objection to the use of the films of the normal brain from the internet for comparison purposes, claiming petitioner was caught off guard or blindsided by the information. Tr. 288-89. However, petitioner was permitted to have Dr. Steinman submit a supplemental report (Pet. Ex. 68) after the hearing, when he had the benefit of the transcript and other information, to address petitioner's objections.

posterior fossa, which is in the middle of the brain. Tr. 277. Its function is to send fibers to the cerebral cortex, which is important for cognition and motor control. Tr. 279. Heavenly's vermis was malformed and hypoplastic. Tr. 278-79; Resp. Ex. X-3. "…it hasn't developed normally. It wasn't destroyed. It just wasn't developed normally." Tr. 278.

Dr. Holmes agreed with Dr. Steinman that "cortical atrophy is a maldevelopment of the brain to form to its full extent," but in this case, the brain just failed to develop. Tr. 261. The corpus callosum is the structure that connects the two hemispheres, or sides, of the brain together; it extends from the back to the front of the brain and is made of myelin. Tr. 267-68. On Heavenly's MRI, the corpus callosum is hard to see because it is so thin. Tr. 283-84. Dr. Holmes explained that Heavenly's thin corpus callosum was due to delayed myelination, which occurs when "there's not enough cells being developed in the brain that are sending axons to the corpus callosum. And, so, the – the myelin is not occurring in a normal fashion." Tr. 269. In Heavenly's case, "the corpus callosum is present but it's very thin. So there are some brain cells there that are sending her axons to the corpus callosum. But the axon – the brain cells are not maturing in a normal fashion." Tr. 269.

Dr. Holmes explained, "[D]emyelination means… myelination disappears. It's destroyed. Delayed myelination is it never formed." Tr. 270. For a vaccine to cause delayed myelination or the inability to produce myelin, the vaccine would have to be given early enough to target the oligodendroglia cells, which form myelin. Tr. 269-70. "But I've never heard of that." Tr. 270. When a vaccine produces inflammation in the brain, as in ADEM, myelin can be destroyed; this appears on MRI as demyelination, not as delayed myelination, which is what is shown in this case. Tr. 272.

Dr. Holmes explained that delayed myelination mainly affects motor activities; children with delayed myelination tend to be hypotonic, with poor muscle control. Tr. 275. However, "when cells in one part of the brain do not talk to cells in the other part of the brain, you get cognitive deficits as well." Tr. 275-76. Myelination allows different parts of the brain to communicate, enabling higher cortical functions such as language, and "makes us a human being." Tr. 276. Delayed myelination can occur without Dandy-Walker variant; "sometimes babies that have had hypoxic ischemic encephalopathy will have delayed myelination." Tr. 276. In Dr. Holmes's opinion, the corpus callosum is a good marker of myelination and delayed myelination, but in Heavenly's case, it is only part of the problem. Tr. 276. Her MRI shows delayed myelination "throughout the brain." Tr. 276.

In Dr. Holmes's opinion, Heavenly's brain failed to grow, rather than being fully developed and later injured. Tr. 283. "…the cerebral dysgenesis here would refer to the fact that the brain is not developing. So there's not necessarily malformed cells in the cerebral dysgenesis. But it's just – it's the lack of brain growth that's occurring." Tr. 285; Resp. Ex. X at 8. Dr. Holmes stated that, if he and his colleagues had to look at this MRI and "predict how the child is doing at age 5 and half months, we would – we would predict doing very, very poorly." Tr. 286.

Dr. Holmes agreed with Dr. Steinman that some children with Dandy-Walker variant can be normal, and, if Heavenly had only Dandy-Walker variant, "we would not be here today." Tr. 272-73; Resp. Ex. M at 1. But, "[c]hildren with vermian hypoplasia and supratentorial

abnormalities in addition to the Dandy-Walker cyst are at very high risk for developmental impairment. Reduced vermis volume is associated with impaired global development, cognition, expressive language, and gross and fine motor skills…." Resp. Ex. M at 1.

Dr. Holmes testified that Heavenly had microcephaly, cerebral dysgenesis, and delayed myelination. Tr. 273. A toxin could not lead to this degree of cerebral atrophy. Tr. 274. If the vaccine at two months of age caused delayed brain maturation and the vaccine at four months of age aggravated it, the MRI in November of 2010 would have reflected T-1 signal abnormalities, signs of necrosis, or changes to the basal ganglia, none of which were seen on Heavenly's MRI. Tr. 274-75. MRIs of children with encephalitis caused by pertussis look "hugely different." Tr. 275. "This is a baby that has – the brain has failed to develop normally. And there's no evidence on the radiologist's report to indicate there has been any type of destructive process whatsoever. This all can be explained by brain maldevelopment. And this began in the first trimester [of pregnancy]." Tr. 275. In Dr. Holmes's opinion, Heavenly's MRI showed a high likelihood that she was destined for significant developmental problems and the likelihood that the DTaP had any relevance to the outcome, low.

4. Dr. McGeady's Opinion

Dr. McGeady commented on Drs. Mauney and Steinman's emphasis on "regression" of milestones after the first set of vaccines on August 2, 2010, stating Heavenly had not yet developed many skills. Resp. Ex. C at 4-5. "Very few skills are normally present early in life, and it is not surprising that a child with significant neurologic impairment but without physical signs thereof would be recognized only when skills fail to develop as the child grow older." *Id.* at 5.

Dr. McGeady further noted that in his report Dr. Mauney relied heavily on the history provided by Ms. Martin, over a year after Heavenly's last immunization. Resp. Ex. C at 5. "Ms. Martin's recollection is at variance with the medical records on several points." *Id.* While Ms. Martin did report that Heavenly slept a lot after the first DTaP vaccine, she did not report any decrease in alertness or poor interaction. *Id.* There was no developmental concern reported on the part of the pediatrician until September 24, 2010, nearly two months after the first DTaP vaccine on August 2, 2010, and before the second vaccination, and no concerns voiced by Ms. Martin until October 1, 2010 after the pediatrician had raised concerns. *Id.* Although Ms. Martin testified that Heavenly was screaming, difficult to feed, and failing to hold her arms up following the second DTaP vaccine, there were no contemporaneous medical records documenting any report or concern about such issues. *Id.* The first report of Heavenly not reaching for things or recognizing people was Ms. Martin's October 1, 2010 phone call, after the concerns she reported were already raised by the pediatric staff at both the September 24th and 28th visits. *Id.*

Dr. McGeady pointed out that Dr. Mauney addressed the decline of Heavenly's head circumference between the August 2, 2010 and the September 28, 2010 vaccinations but failed to address the downward trajectory in Heavenly's head circumference documented in the medical records following her birth and preceding any vaccination with a continued decline thereafter. Resp. Ex. C at 5-6. Her length and weight followed a similar trajectory. *Id.* Therefore, "it is not possible to attribute this failure to thrive to Heavenly's immunizations." *Id.*

Dr. McGeady further questioned Dr. Mauney's opinion on the onset of Heavenly's "injuries" coinciding with the vaccines, again pointing out that Dr. Mauney's opinion was based on Ms. Martin's history provided over a year after the vaccinations and at a time in which Ms. Martin was convinced that the vaccines were the cause of Heavenly's condition. Resp. Ex. C at 6. "The history that she provided is likely to have been influenced by that conviction." *Id*. In Dr. McGeady's opinion the medical records do not support any association of CNS injury with receipt of the vaccines, "but rather suggest a child with congenital CNS deficit who failed to achieve developmental milestones." *Id*. Dr. McGeady further noted Dr. Mauney never addressed Heavenly's Dandy-Walker variant. *Id*. "There are many CNS problems associated with Dandy Walker malformation and its variant form, and we know that she was born with that CNS anomaly." *Id*.

Dr. McGeady turned to Dr. Steinman's opinion that the medical records support an aggravation of neurological damage associated with the receipt of DTaP vaccinations despite the Dandy-Walker variant malformation, submitting his opinion is inaccurate. Resp. Ex. C at 6-7. According to Dr. McGeady, in view of the minimal milestones in the first two months of life, "a child destined to have significant neurologic impairment might appear normal by these minimal criteria early in life." *Id*. Further, both Dr. Steinman and Dr. Mauney relied on the developmental history provided by the family rather than the medical record, and the history given by the family was inaccurate. *Id*.

Dr. McGeady agreed that Dandy-Walker variant can be less severe than Dandy-Walker malformation, with several papers supporting the CNS abnormalities associated with the basic lesion. Resp. Ex. C at 9. For example, "CNS dysgenesis and developmental delay are common in this syndrome, as it reflects a profound disruption of midline developmental field structures." *Id*. Petitioner's theory relied on "the hypothetical possibility of a vaccine which has never been reported to cause this type of gross anatomical abnormality of the brain, doing so in this instance." *Id*. at 10. "The dubious nature of the evidence that the vaccine had any adverse effect systemically or that the child had any loss of developmental milestones rather than a failure to develop beyond certain rudimentary skills must also be considered." *Id*. Dr. McGeady concluded, within a reasonable degree of medical certainty, that the vaccines received by Heavenly on August 2, 2010 and September 28, 2010 were unrelated to her CNS abnormalities and developmental delay. *Id*.

Dr. McGeady found it "incomprehensible," that the vaccines given on August 2 and September 28, 2010, could have aggravated Heavenly's condition to such catastrophic proportions as a result of IL-1β "without something, a very obvious clinical event being seen… that was not the case." Tr. 328-29. Dr. McGeady further pointed out, and Dr. Steinman agreed, there was no evidence in the record that Heavenly suffered convulsions within 72 hours of the either set of vaccinations. Tr. 216, 329. Further, there was no evidence in the record that Heavenly experienced any significant adverse reaction locally at the site of the DTaP injection or by systemic manifestation of fever. Tr. 215-16, 329.

5. Analysis

Petitioners have not established that the vaccines received by Heavenly on August 2 or September 28, 2010 caused, aggravated, or contributed to Heavenly's devastating condition. The

records simply do not support Dr. Steinman's opinion that Heavenly suffered any adverse reactions following either the August 2 or September 28, 2010 vaccinations or that the vaccine she received aggravated her condition in any way. Further, petitioners conceded that Heavenly did not suffer from fever, shock collapse, or convulsions following either set of vaccinations.[53] Tr. 29, 60, 133, 215-16. Heavenly's failure to thrive began in the days following her birth and continued to progress, with the first notation of hypotonia being made by the geneticist in November of 2010 which prompted her admission to the hospital. *See* Pet. Ex. 7 at 1. Petitioners cannot demonstrate that Heavenly experienced any encephalopathic event or the inflammasome reaction posited by Dr. Steinman. At best, the petitioners' evidence supports that, during the summer of 2010, in addition to her failure to thrive, Heavenly experienced gastrointestinal issues with constipation, which was undoubtedly painful for her.

Ms. Martin described an immediate reaction after the September 28, 2010 vaccinations maintaining that position for several years, then added that Heavenly had a reaction following the August 2, 2010 vaccinations as well. However, Ms. Martin did not advise any medical provider of any reactions following Heavenly's vaccination, at the time the reactions allegedly occurred, at any medical visit or phone call thereafter. Even when Dr. Lovlie advised Ms. Martin on September 24, 2010 that she could not get Heavenly to focus, Ms. Martin disagreed responding that Heavenly watched TV at home. *See* Pet. Ex. 3 at 19. One would be hard pressed to accept Ms. Martin's testimony that, several days after the September 28, 2010 vaccinations, Heavenly was inconsolable, not eating, not alert, and was floppy, yet no one else noticed, Ms. Martin, did not call a doctor, did not present Heavenly for immediate medical care, and did not mention it when she called the doctor on October 1, 2010. Tr. 62-67. Ms. O'Quin's testimony that Tim was involved in Heavenly's day to day care and "whatever he would say that would be the truth" lends credibility to the emergency room neurologist reporting that the uncle stated Heavenly was floppy in July or four months ago. This is bolstered by Ms. O'Quin's agreement that "all newborns are kind of floppy" but Heavenly "became more floppy." Tr. 143-44. Further, Ms. Martin testified that she had raised many foster children and admitted that by September 24, she knew something was wrong with Heavenly. Tr. 40-44, 102.

Petitioners cannot establish that an event occurred simply based upon their uncorroborated allegations, especially where the contemporaneous proofs rebut those after-the-fact allegations. Section 13(a)(1); *Cucuras*, 993 F. 2d. at 1528. Controlling law gives greater weight to the written records based on the proposition that individuals are more likely to report observed medical problems or concerns to a medical provider, who in turn would examine and document those concerns, in his or her efforts to provide the best possible care.

To further support their allegations that Heavenly suffered reactions after each set of vaccinations on August 2 and September 28, 2010, petitioners offered the report of Heavenly's treating neurologist, Dr. Mauney.

[53] The only evidence of inconsolable crying in the record was documented by a nurse at Dr. Lovlie's office on November 3, 2010, months after Heavenly's vaccinations, and associated with the constipation suffered by Heavenly Pet. Ex. 3 at 15. Ms. Martin's and Ms. O'Quin's testimony of inconsolable crying after the September 28 vaccines finds no support in the medical records, was not reported to any physician during that time frame, was not accompanied by fever, convulsion, or shock collapse, and was admittedly believed to be associated with her stomach pain and her inability to see. Tr. 54-55, 60-61, 80-81.

It is well established in the vaccine program that "medical records and medical opinion testimony" of treating physicians can be "probative" because "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F3d at 1278). But statements from treating physicians are not sacrosanct and can be rebutted and found by the special master to be unreliable or not dispositive in light of the record as a whole. Section 13(b)(1); *Snyder*, 88 Fed. Cl. at 746 n. 67; *Davis v. Sec'y of Health and Human Servs*., No. 07-451V, 2010 WL 1444056, at *14 (Fed. Cl. Spec. Mstr. Mar. 16, 2010), *aff'd*, 94 Fed. Cl. 53 (2010), *aff'd*, 420 F. App'x 973 (Fed. Cir. 2011).

Dr. Mauney did not see Heavenly until over a year after her vaccinations and diagnosed her with having a metabolic disorder with encephalopathy of unknown origin. *See* Pet. Ex. 10 at 25-26. The opinions contained in his report were based upon facts provided by Ms. Martin, not the medical records. At his first examination, Dr. Mauney wrote that Heavenly's regression began after her four-month-old vaccinations. Pet. Ex. 23 at 2-3. He mentioned the congenital brain anomalies seen on the November 2010 MRI in his initial office record but did not discuss these findings in his report. *See* Pet. Ex. 10 at 25. His report also failed to include the findings and opinions of the neurologist and geneticists who treated Heavenly for the year before he saw her. He failed to acknowledge the drop in head circumference between birth and one month of age, documenting only the drop between two and four months. He further failed to address Heavenly's failure to thrive from birth onward, noting regression after the second set of vaccinations and a fall of development after the first set of vaccinations, with disregard for the content of the medical records. Pet. Ex. 23 at 2-3. Moreover, Dr. Mauney failed to differentiate between Heavenly's failure to meet developmental milestones versus a loss of milestones in arriving at his conclusions that her condition was vaccine-related.

When an expert relies on questionable or rebutted facts, that opinion is properly given less weight. *See Dobrydnev v Sec'y of Health & Human Servs*., 566 F. App'x 976, 983 (Fed. Cir. 2014)(expert's opinion based on facts that were not supported by a preponderance of the evidence were appropriately rejected by special master); *Davis v. Sec'y of Health & Human Servs*., 20 Cl. Ct. 168, 173 (1990); *Raley v. Sec'y Health & Human Servs*., No. 91-732V, 1998 WL 681467, at *7 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) ("the conclusions of an expert are only as sound as their factual predicate"). Accordingly, the conclusions reached by Dr. Mauney, based on Ms. Martin's history alone and inconsistent with the medical records and objective test results, have little probative value and are not remedied by Dr. Mauney's status as a treating physician.

More reliable are the records from Heavenly's treating geneticist and neurologist, Drs. Martinez and Maertens. On November 9, 2010, Dr. Martinez documented that Heavenly was being seen "because of history of developmental delay and microcephaly." Pet. Ex. 7 at 1. "We understand that she has been having abnormal developmental progress, and she was recently seen in the eye clinic and found to have a number of abnormalities of concern including the fact that she was not following light, and the family was told that she needed to be seen by a neurologist." *Id*. Physical examination revealed a hypotonic child who did not follow, was microcephalic with a head circumference of 40 cm, and had a closed anterior fontanel. *Id*. Her pupillary response was very sluggish. *Id*. She had abnormal posture with extension response and very lethargic appearance. *Id*. Her height and weight were in the 25th percentile. *Id*.

Dr. Maertens described Heavenly as a five-month-old with a history of feeding difficulties, developmental delay, and failure to consistently meet developmental milestones. Pet. Ex. 4 at 4. His assessment was microcephaly most likely due to Dandy-Walker variant, cortical atrophy, and corpus callosum thinning per MRI, poor feeding, developmental delay, and suspected genetic or metabolic abnormality or cerebral palsy. *Id*. at 9, 23. He noted head lag, inability to roll over, push up to prone, sit unsupported, or hold her head up while sitting supported. *Id*. She did not track or follow objects, turn in response to noise or readily hold objects. *Id*. He ordered an MRI, which indicated that Heavenly had Dandy-Walker variant, diffuse cortical atrophy, and a thin corpus callosum. *Id*. at 118; Pet. Ex. 9 at 27. Two EEGs performed showed seizure activity. *Id*. at 48; Pet. Ex. 8 at 61, 107. A third EEG done on November 15, 2010 still showed some seizure activity, but improvement. *Id*. at 45-46; Pet. Ex. 8 at 62-63, 108-09. His discharge summary noted a five-month-old with feeding difficulty and developmental delay admitted for consistently failing to meet developmental milestones and a diagnosis of microcephaly, developmental delay, seizure disorder, and cerebral dysgenesis. *Id*. at 4; Pet. Ex. 8 at 11-13; Pet. Ex. 9 at 24. There was no mention of or attribution of her condition or encephalopathy to any vaccines by any of the treating physicians.

The experts in this case are highly credentialed and respected in their fields. Dr. Steinman routinely testifies in the program and his research and achievements in multiple sclerosis are well known. While he was involved in research regarding pertussis vaccine in his earlier work, in the past decade or more he has focused on research and administrative duties and less on patient care. *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *7 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). Dr. Steinman was offered as an expert in neuroimmunology in this case. Though his resume notes his position as the "George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics and Pediatrics," little was mentioned about his experience in pediatrics and even less about his experience with infants born with Dandy-Walker variant and the associated anomalies present in this case. *See* Pet. Ex. 30 at 1. That was evident in his unyielding position that babies born with Dandy-Walker variant can be normal, even while admitting that this child was born with multiple anomalies, each of which rendered the outcome for this child more dire, and yet refusing to admit that the gravity of this child's condition was due to her brain malformations. Dr. Steinman maintained his opinion that neuronal damage caused by the pertussis vaccine leads to demyelination when the MRI in November of 2010 reports the brain's failure to show myelination. He failed to explain how a failure to myelinate or delay in myelination could result from a vaccine and how pertussis toxin causing neuronal damage could be responsible for the absence of normal brain anatomy. Dr. Steinman further maintained that Heavenly lost milestones at two and four months of age, when the milestones he referred to had not yet been reached. Tr. 195-96.

Dr. McGeady, on the other hand, became board-certified in pediatrics in 1973, with a second board in allergy and immunology in 1975. Resp. Ex. D at 1. He is well-versed in pediatrics and immunology and gave deference to Dr. Steinman's theory but cogently explained that, while whole cell pertussis toxoid has certainly been shown to cause encephalopathy, the acellular less so, there was nothing provided in this case or in any of the literature to support how congenital brain abnormalities to the extent present in this case could be caused by pertussis or vaccination. Dr. McGeady was further steadfast on child development and Heavenly's failure to meet normal and expected milestones.

Dr. Holmes, like Dr. McGeady and Dr. Steinman, is well known to the program. Dr. Holmes specializes in child neurology as well as teaches neurological sciences and pediatrics. His practice focuses on pediatric neurology treating children with neurological deficits associated with various brain anomalies. He has experience treating children with Dandy-Walker malformations. Tr. 235. Dr. Holmes's testimony was informative and understandable and described the findings on the MRI; in this case, the extent of the brain's failure to develop, and the effect of that failure on the neurodevelopment of this infant. He further explained encephalopathic events following vaccines and pointed out that signs of an encephalopathic event were not documented in this case nor reported by the caretakers.

I find the facts, medical records, and literature more supportive of the opinions rendered by Dr. Holmes and Dr. McGeady that Heavenly's failure to thrive, failure to meet milestones, microcephaly and progressive decline in neurological development were associated with her Dandy-Walker variant and accompanying brain abnormalities. Dr. Steinman's theory that the pertussis toxoid caused neuronal death/damage resulting in convulsions, seizures, and encephalopathic events following the August 2 and September 28, 2010 vaccinations has no support in the record. Little weight was given to Dr. Mauney's opinion. Dr. Mauney relied on the facts provided by Heavenly's caretakers rather the medical records. His report conflicted with his own treatment records and assessments of Heavenly during the course of his care. And, most conspicuously, Dr. Mauney failed to address Heavenly's failure to thrive or the MRI results showing Dandy-Walker variant and other congenital brain abnormalities.

Accordingly, petitioners have failed to satisfy *Althen* Prong 2/*Loving* Factor 5.

C. *Althen* Prong 3/*Loving* Factor 6: Proximate Temporal Relationship

Petitioners have not demonstrated a medically acceptable timeframe to explain the clinical course of Heavenly's injury as a result of the August 2 and/or the September 28, 2010 vaccinations.

Dr. Steinman opined that pertussis toxin can cause an encephalopathic event within 72 hours to one week of vaccination. Tr. 182. He agreed that signs of an encephalopathic event include fever, convulsions, inconsolable crying, and shock collapse. Tr. 215-16. He further opined that the effects of aluminum caused an innate immune system response within three days of the September 28, 2010 vaccinations, when Heavenly experienced inconsolable crying. Tr. 214-15; Pet. Ex. 29 at 8. He agreed there was no evidence that Heavenly suffered fever, shock collapse, inconsolable crying, or convulsions within 72 hours of her vaccinations. Tr. 216. However, Dr. Steinman stated the description of Heavenly as floppy following her four-month-old vaccinations fits with the timing of a pertussis injury. Tr. 182. Based on the testimony he heard from Heavenly's caretakers, Dr. Steinman believed she had a classic pertussis reaction, with inconsolable crying within 72 hours to a week after immunization. Tr. 182. This timing "fits quite well" with the information in the pertussis vaccine package insert. Tr. 182. Dr. Steinman concluded that though the information after the two-month vaccinations is a bit "fuzzier" with the description of Heavenly sleeping all of the time, "I think that the two-month vaccine was a trigger, and the four-month vaccine definitely. And then the head circumference really plummeted between month two and month four." Tr. 183. He testified that was another important marker. Tr. 183.

Dr. McGeady addressed Dr. Mauney's opinion on the onset of Heavenly's "injuries" coinciding with the vaccines, pointing out that Dr. Mauney's opinion was based on Ms. Martin's history provided over a year after the vaccinations. Resp. Ex. C at 6. Dr. McGeady disagreed with Dr. Steinman's opinions opining the medical records do not support any association of CNS injury with receipt of the vaccines, "but rather suggest a child with congenital CNS deficit who failed to achieve developmental milestones." *Id*.

Dr. Holmes, like Dr. McGeady, found no support in the record for any vaccine-related reaction or injury following either set of vaccinations.

As discussed at length above, there was no reported reaction following either of the two sets of vaccinations in the medical records. Heavenly was seen by her pediatrician at visits following each set of vaccines, with no reports of any untoward events in the days following the vaccinations. Although Ms. Martin testified to picking up Heavenly from her car seat three or four days after the September 28 vaccinations and finding her to be floppy, she did not contact the pediatrician, did not take Heavenly to the emergency room, did not believe that Ms. O'Quin or Angela even noticed, and never mentioned it to the medical provider in any subsequent phone calls or visits. Tr. 62-67. The only mention of "floppy" in the record was from the attending neurologist after he spoke with Tim upon Heavenly's admission in November of 2010, who stated Heavenly was floppy in July prior to either set of vaccinations.

Petitioners' inability to corroborate their allegations of immediate vaccine reaction and process of injury without any medical record proof further diminishes their argument that the injury occurred and/or was aggravated within a reasonable timeframe following the August 2 or September 28 vaccinations. Petitioners cannot provide a temporal relationship between the vaccinations and the manifestation of developmental injury because the record is replete with Heavenly's ongoing failure to thrive, diminishing head circumference, and failure to attain developmental milestones from the time of her birth. Therefore, petitioners have not satisfied *Althen* Prong 3/*Loving* Factor 4.

D. *Loving* Factor 1: Heavenly's Condition Prior to Her Vaccinations

Although Heavenly appeared normal at birth, her medical records indicated that, beginning in the first days of life, she had difficulty feeding and struggled to gain weight. Her birth weight of six pounds, 12 ounces initially placed her in the 25th percentile for weight; however, she lost ten ounces in the first three days of life, and at weight checks on July 26 and August 2, 2010, she had fallen to the 10th and 2nd percentiles, respectively. *See* Pet. Ex. 2 at 6; Pet. Ex. 67 at 2, 4. Heavenly was presented to the Baldwin County Health Department regularly for weight checks due to her difficulty gaining weight. *See generally* Pet. Ex. 67. Heavenly had difficulty latching and was transitioned to a combination of formula and breastmilk. *Id*. at 2, 4.

During this time, Heavenly's head circumference dropped from the 50th percentile at birth to the 25th percentile at her one month and two month, June 28, 2010 and August 2, 2010 visits. Pet. Ex. 2 at 49; Pet. Ex. 3 at 23-24.

At her two-month well-child check-up on August 2, 2010, Heavenly was noted to have

poor weight gain; her mother was instructed to return her in two weeks for a weight check. Pet. Ex. 3 at 23. She received her first round of DTaP, Hib, IPV, rotavirus, and Prevnar vaccinations at this visit. *Id*.

E. *Loving* Factor 2: Heavenly's Condition Following Her Vaccinations

Between August 2, 2010 and September 28, 2010, Heavenly struggled to gain weight and her head circumference continued to fall, and she was noted to be unable to focus by the pediatrician on September 24, 2010 and September 28, 2010. *See generally* Pet. Ex. 3. Following Ms. Martin's telephone call to the pediatrician on October 1, 2010, in which she repeated the doctor's concerns of not reaching for things and not recognizing people, Heavenly was examined by an ophthalmologist. Pet. Ex. 3 at 17; Pet. Ex. 5 at 15-16. In November of 2010, Heavenly saw a geneticist, who recommended a neurological workup. Pet. Ex. 7 at 1. The pediatric neurologist, Dr. Maertens, ordered an MRI, which showed that Heavenly had Dandy-Walker variant, vermian hypoplasia, cerebral dysgenesis and a thin corpus callosum. Pet. Ex. 4 at 4, 9, 118-19.

Heavenly continued to struggle with anemia, weight gain, and malnutrition, as well as other gastrointestinal issues, including esophagitis, hiatal hernia, ulcer, and gastric bleeding. Pet. Ex. 9 at 6-7, 15-16; Pet. Ex. 12 at 40, 43, 46; Pet. Ex. 13 at 15-21; Pet. Ex. 55 at 206, 242, 250, 263-66, 274-75, 292-95; Pet. Ex. 59 at 7-8, 231-32. She was repeatedly assessed with developmental delay and failure to thrive. Pet. Ex. 3 at 5; Pet. Ex. 4 at 4, 9; Pet. Ex. 9 at 24; Pet. Ex. 10 at 22; Pet. Ex. 12 at 46, 52, 55. Her condition deteriorated, and she passed away on January 2, 2020. Pet. Ex. 75 at 1.

F. *Loving* Factor 3: Significant Aggravation

In light of Heavenly's subsequent health problems and eventual death, it is inarguable that her post-vaccination condition appeared markedly worse than her pre-vaccination condition. Thus, Heavenly experienced a significant aggravation as defined by the Federal Circuit in *Sharpe*. 964 F.3d at 1082 ("Thus, *Loving* prong 3…only requires a comparison of a petitioner's current, post-vaccination condition with her pre-vaccination condition.").

However, the Federal Circuit also stated that, "if the evidence as a whole ultimately shows that the vaccine was not a substantial factor in causing the petitioner's injury, then compensation should be denied." *Sharpe*, 964 F.3d at 1082. Here, the petitioners have failed to show that the subject vaccinations played any role in causing or aggravating Heavenly's condition. As discussed in detail above, Dr. Steinman's proffered theory that the pertussis toxin caused extensive neuronal death, resulting in the findings on Heavenly's MRI at five months of age, was not persuasive. Rather, it is more likely than not that, as Dr. Holmes explained, Heavenly's brain failed to fully develop in utero, and the resultant deficits were not apparent until she failed to meet normal developmental milestones. Further, as Dr. McGeady pointed out, for a vaccine to cause such devastation there would have to have been some reaction following the vaccination, none of which was documented in the medical record. Accordingly, I find that the DTaP vaccinations did not significantly aggravate Heavenly's pre-existing Dandy-Walker variant and other brain abnormalities.

VI. Conclusion

When petitioners fail to carry their burden, the Secretary is not required to present an alternative expression for the vaccinee's injury. *De Bazan*, 539 F.3d at 1352. The petitioners in this matter have failed to put forth a prima facie showing of causation; therefore, respondent is not required to demonstrate that a "factor unrelated" was the sole cause of petitioner's injury. However, he clearly and cogently did. Heavenly was born with congenital and devastating brain abnormalities from which she suffered the results well-documented in medical literature.

Petitioners have not put forth preponderant evidence that the vaccines received by Heavenly on August 2, 2010 and/or September 28, 2010 caused and/or significantly aggravated her condition. Therefore, petitioners have not demonstrated entitlement to compensation and the petition must be dismissed.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master